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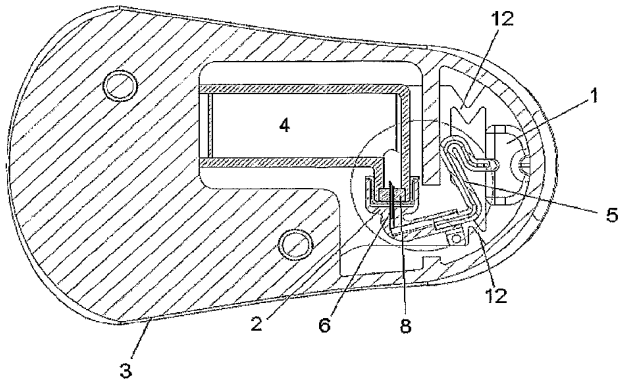

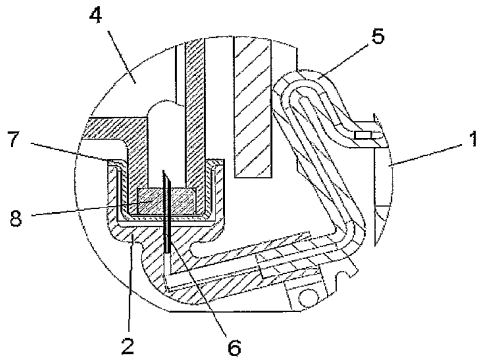

(57) Abstract: The application relates to a device for an intermittent or continuous administration of a therapeutical substance, such as insulin, comprising a base part to which an injection part and a delivery part (3,4) are fastened. The delivery part comprises a reservoir and a pump, and the injection part comprises base plate (10), a cannula part (1) with a body with a through-going opening, and at least one cannula having a proximal end protruding from the lower side of the body and means for fastening the base plate (10) to the skin of the user. The device is characterized in that the delivery part (3, 4) and the injection part is assembled through a connector (2) comprising a fluid path leading fluid from the reservoir (4) to the through-going opening in the cannula part (1, 1 b) which fluid path comprises means (7, 8, 8b, 8c) for blocking access to the injection part when the connector (2) is disconnected from the delivery part (3, 4) and/or the injection part.

WO 2007/071258 A1

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Injection device

The technical field

The invention relates to a device for an intermittent or continuous administration of a therapeutical substance, such as insulin, comprising a base part to which an injection part and a delivery part are fastened. The delivery part comprises a reservoir and a pump, and the injection part comprises a body with a through-going opening, and at least one cannula having a proximal end protruding from the lower side of the body.

Prior art

EP-A1-1.527.792 describes a medical device comprising a transdermal access unit and a reservoir. The transdermal access unit comprises transdermal access means for transporting a fluid through a skin portion of a subject, and a mounting surface adapted for application to the skin of the subject. The reservoir unit comprises a reservoir adapted to contain a fluid drug and an outlet allowing the transdermal access means to be arranged in fluid communication with an interior of the reservoir. Also the device comprise means for expelling e.g. a pump which means during use expels a fluid drug out of the reservoir and through the skin of the subject via the transdermal access means. The transdermal access unit and the reservoir unit further comprise releasable mating coupling means allowing the reservoir unit to be secured to the transdermal access unit during use. The object of the invention is to provide a skin mountable drug delivery device or system which allows such a device or system to be used in a convenient and cost-effective manner.

According to this document the insertion needle (113, 212 or 412) of the described embodiments is pivotably arranged inside the needle housing and can be moved between an extended and an extracted position. When the injection needle is inserted it penetrates a membrane in order to penetrate the skin of the subject. According to the present invention a subcutaneously

placed cannula is stationary in relation to the base part of the device where the base part is somehow adhered to the user.

US 2004/0204673 A1 describes a lightweight and low cost fluid delivery device capable of adjustable and programmable fluid delivery includes a housing that surrounds a reservoir chamber. In fluid communication with the reservoir chamber is a dispenser for dispensing the fluid from the reservoir in finite amounts. The dispenser is controlled by an electronic microcontroller of the fluid delivery device. The fluid delivery device further includes a communication element that receives information from a remote control device not mechanically attached to the fluid delivery device of the present invention. Also included is an exit port assembly in fluid communication with the dispenser from which the liquid medication exits the fluid delivery device and enters the body of a mammalian patient transcutaneously.
The housings 702, 802 can each be made from flexible material, or can be provided with flexible hinged sections that allow the fluid delivery device 10 to flex during patient movement to prevent detachment and aid in patient comfort but there are no directions as to how such a hinged section should be constructed.

The invention

The object of the invention is to provide a device for delivering fluid including a pump, a reservoir and an injection part which device assures a fluid tight connection between the reservoir and the injection part. The devices according to the present invention are constructed with means to provide an easy connection and disconnection of the delivery parts to the injection part and at the same time assure a fluid tight connection and prevent invasion of microorganisms into the parts of the device. According to a preferred embodiment of the invention it is also assured that the wearer will have less discomfort during use of the device as this embodiment has means to reduce the transferal of actions from the relatively heavy delivering part to the injection part when the delivering part is affected by touches or movements.

According to claim 1 the invention comprises a device for delivering fluid comprising an injection part and a fluid delivery which fluid delivery part and injection part can be separated and rejoined part (3, 4), the fluid delivery part comprises a reservoir, transferal means e.g. in form of a pump and a house and the injection part comprises

- a base plate,
- a cannula part comprising a body with a through going opening provided with a cannula extending past the proximal side of the base plate and
- means for fixation of the base plate to the skin of the user

wherein the delivery part and the injection part is assembled through a connector comprising a fluid path leading fluid from the reservoir to the through-going opening in the cannula part which fluid path comprises means for blocking access to the injection part when the connector is disconnected from the delivery part and/or the injection part. According to one embodiment of the invention the device comprises means for blocking the access to the delivery part when the connector is separated from this. This embodiment is normally used when a reservoir of the delivery device can be removed from the injection part and afterwards mounted again for further use. According to this or other embodiment the base plate is provided with fastening means for connecting and disconnecting of the delivery device extending from the distal side of the base plate.

When the connector is a part of the device it is possible to provide a fluid tight connection between the delivery part and the injection part. When constructing the device with and interconnecting part it is also possible to add other advantageous features such as means for reducing impacts transferred from the heavy delivery part to the injection part which is partly inserted into the skin of the user. These features make it more safe and comfortable for the user to wear the device.

A "reservoir" is the part of a device where the liquid is held, the liquid being any kind of medication which has to be delivered to the patient in a certain

amount at certain time intervals. The "delivery part" is the part of the device which holds a liquid storage and assures transport of the liquids to the injection part. The "injection part" defines a kind of port which is fastened to the user's skin and provided with means e.g. a cannula for transferring the liquid to the user. The injection part does not comprise any heavy or voluminous parts.

In a preferred embodiment the end openings to the fluid path through the connector are blocked when the connector is disconnected from the delivery part and/or the injection part. This feature is directed toward products which are intended to be used for a longer time which necessitates that the reservoir can be replaced and e.g. the delivery part can be disconnected. Preferably the openings to the fluid path through the connector are blocked with a membrane which can be penetrated by a needlelike object.

In another preferred embodiment the parts of the device have at least two positions, a first position and a second position, in the first position the outlet from the reservoir is blocked with a first barrier which is not permeable for microorganisms and the inlet of the through going opening in the injection part is blocked with a second barrier which is not permeable for micro organisms, in the second position an open fluid connection is formed between the reservoir and the through going opening in the injection part by passing the first and the second barrier. One or both of the barriers can comprise a material which can be penetrated by a needlelike object where the opening close on retraction of the needle like object or one or both of the barriers can comprise a hard surface which in one position forms an opening in the area positioned between the outlet of the outlet pipe and the inlet of the through going fluid path and in another position close the through going fluid path. Preferably the injection part and the delivery part are connected to each other by one or more flexible areas. More preferred the connector is connected to one part by one or more non-flexible connection and connected to the other part by a flexible area. Most preferred the connector is connected to the injection part by a flexible area.

In one preferred embodiment the at least one flexible area is constructed of an area with reduced material dimensions.

In another preferred embodiment the at least one flexible area is constructed of an area made by a softer and more flexible material.

In a third preferred embodiment the at least one flexible area is constructed of an area made of a material which by its form has an ability for extension and compression such as a material being pleated or folded.

Preferably the injection part and the delivery part are not connected to each other by non-flexible or rigid areas as this would reduce the effect of the flexible areas. That the injection part and the delivery part are not connected to each other by non-flexible or rigid areas means that only flexible areas connect the injection part and the delivery parts.

In a preferred embodiment the device comprises a base part fastened to the patient's skin, the delivery part is fastened to a first part of the base part and the injection part is fastened to a second part of the base part, one or more flexible areas are positioned between the first part and the second part of the base part. Preferably the delivery part is releasably fastened to the base part, and the connector is unreleasably fastened to the base part. Also the connector is preferably fastened to the first part of the base part and more preferred the connector is fastened unreleasably to the first part of the base part with a non-flexible connection. In the described embodiments the base part is illustrated as a relatively flat part but the "base part" could be any construction which makes it possible to unite or combine the injection part and the delivery part into one unit which unit can be worn by the user directly fastened to the skin.

When the flexible areas are placed between the relatively heavy delivery device and the injection device, the transferal of actions from the delivery

device to the injection device is prevented or at least significantly reduced, and the injection site of the subcutaneously placed cannula will be protected from the main part of any interaction resulting from pushing or touching the delivery part. Often the delivery part is separated physically from the injection part by a relatively long tube which prevents the transferal of actions but when the delivery part is positioned together with the injection device, the user will feel less discomfort when wearing a device according to the invention. By using a connector it is possible to avoid the direct contact between the delivery part and the injection part and at the same time fastened both parts as one unit to the skin of the user.

The cannula can protrude from the proximal side of the body of the injection part or from the side of the body. If the cannula protrudes from the side of the body as it does in the embodiments shown in fig. 4 and fig. 7, the cannula will normally be bending and it would be preferred to use a cannula which is at least partly formed of a soft and flexible material. If the cannula protrudes from the proximal side of the body as shown in fig. 12, the cannula can be made of a hard material such as metal or it can be made of a soft and flexible material.

According to the invention the connector needle can be one end of a single needle which at the other end functions as the cannula. When the connector needle and the cannula is formed as one needle it will normally be made of metal or hard polymer but it can also be made of e.g. a polymer which is hardened in the connector end and unhardened and soft in the cannula end. Also the single needle can be composed of two different materials, a hard material for the connector end and a relatively soft material for the cannula end. Also the connector needle and the cannula can be separated into at least two needles. The injector part can then be provided with a commonly known soft cannula which cannula can be inserted by the help of an insertion needle attached to a separate inserter, and the connector needle can be made of a hard material and fastened to either the injector part or the delivery part.

The flexible areas are constructed of an area with reduced material dimensions, e.g. openings or cuts can be provided in a material or the thickness of a material can be reduced, or of an area made by a softer and more flexible material or it is constructed of an area made of a material which by its form or structure has ability for extension and compression such as a material being pleated or folded.

Preferably access of micro organisms to the reservoir during a non-connected state, i.e. when the reservoir and the injection part are separated, is prevented as the opening to the reservoir is blocked when the two parts separate.

The word "passing" comprise all possible ways to make a flow pass through or around a barrier, in most of the embodiments of this invention the barrier is passed by penetrating the barrier with a needle but there is also an example (fig. 18A and B) where the barrier is passed by pushing aside a hard cover thereby creating a flow path.

If the barriers comprise a material which can be penetrated by a needlelike object, the opening close on retraction of the needle like object. The needlelike object can be either blunt or sharp-pointed meaning that the needlelike object either pushes its way through the barrier or cuts its way through the barrier. If one of the barriers comprises a hard surface, i.e. a non-penetrable surface, the barrier will have to be moved in order to form an opening in the area positioned between the outlet of the outlet pipe and the inlet of the through going fluid path.

In a most preferred embodiment the device is fastened to the patients skin by applying a mounting pad adhered to the proximal side of the base part or to the proximal side of the infusion part, the adhering of the mounting pad to the base part or infusion part can include glue, Velcro, moulding etc.

Embodiments of the invention will now be described with reference to the figures in which:

Figure 1 shows a first embodiment of the invention from above at the B-B line shown in figure 3, where the delivery part is placed beside the injection part.

Figure 2 shows an enlarged part, marked with a circle, of the embodiment in figure 1.

Figure 3 shows the embodiment of figure 1 from the side indicating the line B-B.

Figure 4 shows the first embodiment where the delivery part is separated from the injection part.

Figure 5 shows an enlarged part, marked with a circle, of the embodiment in figure 4.

Figure 6A shows a second embodiment of the invention seen from the side of the injection part.

Figure 6B shows the same embodiment as in figure 6A seen from the cut made by the line B-B.

Figure 7 shows an enlarged part, marked with a circle, of the embodiment in figure 6B.

Figure 8A shows the injection part and the base part of the second embodiment separated from the delivery part.

Figure 8B shows an enlarged part, marked with a circle, of the embodiment in figure 8A.

Figure 9 shows both the delivery part and the injection part of the second embodiment.

Figure 10A shows the same embodiment as figure 8A from a different angle.

Figure 10B shows an enlarged part, marked with a circle, of the embodiment in figure 10A.

Figure 11 shows a third embodiment of a delivery device according to the invention in a connected state, and in this embodiment the delivery part is placed on top of the injection part.

Figure 12 shows the third embodiment of the device in a separated state.

Figure 13 shows the two parts of the third embodiment from the upper and lower side respectively.

Figure 14 shows a fourth embodiment of the delivery device according to the invention. "A" shows the delivery part with the injection part prepared to be connected with the delivery part seen from the side, "B" shows the delivery part from beyond and "C" shows the injection part seen from above.

Figure 15 shows the fourth embodiment seen from the side (line V-V) in a separated state.

Figure 16 shows the fourth embodiment seen from the side (line V-V) in a connected state.

Figure 17 shows a fifth embodiment of the delivery device according to the invention having a fluid tight lock between the delivery part and the injection part.

Figures 18A and 18B show an enlarged part of the fifth embodiment in two states; in the first state the device is closed for fluid flow, in the second state the device is open for fluid flow.

Figure 19 shows another embodiment ensuring fluid tight transferal of fluid from the delivery part to the injection part.

Figure 20 shows a sixth embodiment having a base part equipped with a central connector and peripheral injection part.

Figure 21 shows the delivery device and the base part of the sixth embodiment in a joined state from above and from the side.

Figure 22 shows a cut through view of the sixth embodiment in the joined state of fig. 21.

Figure 23 shows an enlargement of the connector part of fig. 22.

Figure 24 shows an enlargement of the injector part of fig. 22.

Figure 25 shows a view from below of the delivery part of the sixth embodiment.

Figure 26 shows a seventh embodiment having a base part equipped with a central combined connector and injection part.

Figure 27 shows the delivery device and the base part of the seventh embodiment in a joined state from the side and from above.

Figure 28 shows a cut through view of the seventh embodiment in the joined state of fig. 27 and an enlargement of the combined connector/injection part.

Figure 29 shows a view from below of the delivery part of the seventh embodiment.

Figure 30 shows an eighth embodiment having a base part equipped with a central combined connector and injection part where the combined part is divided into to units.

Figure 31 shows the delivery device and the base part of the eighth embodiment in a joined state from above and from the side.

Figure 32 shows a cut through view of the eighth embodiment in the joined state of fig. 31 and an enlargement of the combined connector/injection part.

Figure 33 shows a ninth embodiment having an oval base part equipped with a central connector and peripheral injection part.

Figure 34 shows the delivery device and the base part of the ninth embodiment in a separated state from below and the reservoir and the base part from the side.

Figure 35 shows the delivery device and the base part of the ninth embodiment in a joined state from the side and from above.

Figure 36 shows a cut through view of the ninth embodiment in the joined state of fig. 35 and an enlargement of the injection part.

Fig. 1-3 show a first embodiment of the invention where the delivery part and the injection part are fastened to each other. In fig. 1 the embodiment is seen from above at the B-B line shown in fig. 3 and fig. 2 show a small part of fig. 1 in enlarge form. The device comprises an injection part 1, a connector 2, a delivery part comprising a pump 3 and a reservoir 4, a flexible tube 5 creating a fluid connection between the injection part 1 and the delivery part, a connector needle 6 which can penetrate both a protective seal 7 covering the entrance of the connector and a septum 8 covering the entrance of the reservoir and a cannula 9 which is placed subcutaneously during use. In fig. 1-3 the device is in a connected state where the injection part and the delivery part are joined together and ready for use.

Fig. 2 shows an enlargement of the connector 2 of fig. 1. In this embodiment the connector 2 comprises a molded part in a non-flexible material with a through-going opening which in one end is connected to the flexible tube 5 and in the other end is provided with a connector needle 6. In a state where the connector 2 is not connected to the reservoir 4, the connector needle 6 extends into a closed room comprising walls formed respectively of a cylindrical extension of the connector 2 and of the elastic protective seal 7. In

the connected state the protective seal 7 is pushed towards the inside wall of the connector 2 surrounding the connector needle 6 and when connecting the connector 2 to the reservoir 4 the connector needle 6 first penetrates the protective seal 7 and then the septum 8 in order to create a passage from the connector 2 to the inside of the reservoir 4. In this embodiment the connector 2 is fastened unreleasably to a base plate which is an integrated part of the delivery part 3, 4.

Fig. 3 shows the embodiment of fig. 1 from the side as it would look when the device is in use. A base plate 10 is placed along the skin of the patient and fastened to the patient e.g. by an adhesive pad. The cannula 9 protrudes from the proximal side of the base plate below the injection part 1 and injection part is covered by a housing part. The delivery part 3, 4 is fastened to the distal side of the base plate 10 beside the injection part 1 and is also covered with a housing part.

The base plate 10 will normally at the proximal side be fastened to the patient by an adhesive part or layer but any kind of mounting which will make the base plate stick to the patient without allowing the device to move can be used. The adhesive part or layer can be fastened to the base plate 10 by glue, Velcro, molding or the like.

In a preferred embodiment the delivery part is fastened to the distal side of the base plate 10 by one or more magnets which are embedded in the base plate 10. The detachable delivery part has corresponding magnets which keeps the delivery part in position during use. By means of the magnets of the base plate 10 and/or the delivery part 3, 4 it will be possible to detect conditions of the system such as whether the delivery part is secured properly, if the flow through the device is OK, how long has the delivery part been fastened to the base plate, size of the volume which has passed the device, etc.

Fig. 4 shows the first embodiment in a separated state where it is possible to see the base plate 10 to which the injection part 1 is fastened, objects 11 for fastening of the delivery part to the base part 10 and a flexible portion 12 of the base plate. In order to fastened the delivery part to the base part 10 the delivery part 3, 4 is pushed down towards the base part 10 from above. The flexible portion 12 is constructed of two thin connections formed as straight lines and made by removing material from the plane of the base part 10. This construction of the base part 10 together with the flexible tube 5 allows the injection part 1 which is attached to the cannula 9 to remain in a stationary position although the part of the base part 10 to which the delivery part is fastened is touched or pushed or just moves as a result of the movements of the user.

Fig. 5 shows an enlargement of a part of the first embodiment of fig. 4. Fig. 5 shows in greater detail how the cannula 9 is held in position by the injection part 1; the injection part 1 via the flexible tube 5 is connected to the connector 2. The connector 2, which is fastened to the base part 10 on the same side of the base part 10 as the delivery part, is shown in a transparent form which makes it possible to see the connector needle 6. The connector 2 is preferably made of PP, ABS or similar materials.

In the first embodiment described in fig. 1-5 one of the flexible areas between the delivery part 3, 4 and the injection part 1 is formed by the flexible tube 5. The flexible tube can be produced as a piece of extruded tube, and can be made of PUR (polyurethane), PP (polypropylene), PE (polyethylene), silicone or any other material which is adequately flexible or can be brought into a flexible form e.g. by providing the tube with folding.

The cannula 9 which is integrated with the infusion part 1 and fastened unreleasably to the base part 10 can be inserted subcutaneously either by the help of an inserter or manually.

The house of the delivery part 3, 4 is made of a relatively hard material such as PP or ABS (Poly (Acrylonitrile, Butadiene, Styrene)) which makes it possible for the house to resist impacts of the surroundings.

Fig. 6A shows a second embodiment of the device for delivering fluid according to the invention seen from the side facing the injection part. Fig. 6B shows the same embodiment seen from a cut through the device at the line B-B. Fig. 7 shows an enlargement of the part of the embodiment connecting the injection part 1 to the delivery part 3, 4 through the connector 2. In fig. 6A, 6B and 7 the delivery part and the injection part are both connected to the base part 10 which is the state of the device when in use.

In the second embodiment the injection part 1 is connected to the delivery part 3, 4 by a flexible tube 5 which in this embodiment is formed as a bellows and preferably is made of silicone, PUR, PP/PE or the like. The flexible portions 12 of the base part 10 is formed as relatively thin V-shaped connections made by removing material from the plane of the base part 10. The flexible portions 12 can also be constructed of another material e.g. TPE: This embodiment is provided with sliding rails 11 acting as objects for fastening of the delivery part 3, 4 to the base part 10. In this embodiment the connector needle 6 is fastened to the delivery part 3, 4. The connector needle 6 penetrates a septum 8 when the delivery part is joined to the connector 2 and thereby creates a flow path from the reservoir 4 to the cannula 9.

Fig. 8A and 8B shows the embodiment in a state where the delivery part 3, 4 is separated from the base part 10 which makes it possible to see the two sliding rails 11.

In fig. 8B is shown an enlargement of the connector 2 of fig. 8A. In this embodiment the connector 2 comprises a molded part in a non-flexible material with a through-going opening which in one end is connected to the flexible tube 5 and in the other end is provided with a septum 8. The flexibility

of the flexible tube 5 can be obtained be using a soft and flexible material but in this embodiment the flexibility of the tube 5 is obtained by constructing the flexible tube 5 of a stable – that is a rather rigid – and corrugated material. The reservoir 4 is provided with a connector needle 6 and a cylindrical extension which extension protects the connector needle 6 and can be provided with a protective seal (not shown in fig. 8B). In a state where the connector 2 is not connected to the reservoir 4, the connector needle 6 extends into a closed room comprising walls formed of the cylindrical extension of the reservoir 4 and possibly of an elastic protective seal. In the connected state the protective seal if present is pushed towards the inside wall of the reservoir 4 surrounding the connector needle 6 and when connecting the connector 2 to the reservoir 4 the connector needle 6 first penetrates the protective seal and then the septum 8 in order to create a passage from the reservoir 4 to the inside of the connector 2. In this embodiment the connector 2 is fastened unreleasably to the base plate 10 which is an integrated part of the delivery part 3, 4.

Fig. 9, 10A and 10B also show the device according to the second embodiment of the invention. Fig. 9 shows the delivery part 3, the base part 1 and the injection part 1 and how they are positioned relatively to each other just before they are being joined and an arrow indicates the direction of movement when the delivery device 3, 4 is fastened to the objects 11 of the base part 10 in order to form a connection to the injection part 1. Fig. 10A shows the same embodiment as figure 8A from a different angle and fig. 10B shows an enlargement of the connector 2, marked with a circle, of the embodiment in figure 10A. In this embodiment the cannula 9 protrudes laterally from the injector device and has been inserted perpendicularly to the users' skin. If the cannula 9 is made of a soft and flexible material it is necessary to use an insertion needle to penetrate the skin of the user. This can be done manually by providing the device with an insertion needle protruding through the proximal opening of the cannula 9. The sharp insertion needle exits from the proximal end of the cannula 9 and it is either entering the distal end of the cannula, e.g. through a septum covering the distal

opening of the cannula 9, or it is entering the cannula through the side. In case the insertion needle enters the cannula 9 through the side it is necessary to provide the entering position with some kind of a closure in order to prevent micro organisms to enter the device when the insertion needle is removed after insertion. This embodiment of the device can be inserted with an inserter e.g. the inserter known from PCT application no. DK2005/050010 filed on December 9, 2005. If the cannula was protruding from the proximal side of the injection part it could e.g. have been inserted with the inserter known from PCT application DK02/00640 filed on September 27, 2002.

Fig. 11 illustrates an embodiment where the delivery part 3, 4 is placed on top of the injection part 1. In this embodiment the delivery part is fastened releasably to a portion of the base part 10 which surrounds the injection part 1. The flexible portion 12 of the base part placed around the injection part is formed as a circular folded material which is either the same material as the central part of the injection part in a thinner form of a different material of a more soft or flexible nature. In fig. 11 the delivery part 3, 4 and the injection part are joined together as they would be when the device is in use and a connection which allows for fluid to flow from the reservoir to the cannula 9 is formed. The left and the right versions show views of two different cuts along the lines D-D and E-E respectively at perpendicular angels through the device. In this embodiment the objects 11 for fastening of the delivery part 3, 4 to the injection part are formed as circular profiles standing upright from the base part 10 and having an outward projection which objects 11 fit with corresponding projections 13 on the delivery part. When the delivery part 3, 4 is to be fastened to the injection part 1 two handle portions 14 are pushed together which makes the corresponding projection move outwards and allow the injection part to enter the central opening in the delivery part 3, 4. When the user let go of the handle portions 14 the corresponding parts return to the more central position and locks the injection part 1 to the central opening of the delivery part 3, 4.

The delivery part 3, 4 is combined with a connector 2; the connector 2 has a through-going connector needle 6 and is influenced by a spring 15. When the user pushes the delivery part 3, 4 towards the injection part 1, the spring 15 is compressed and the through-going connector needle 6 is forced through a septum 8a protecting the content of the reservoir from being infected with micro organisms. At the same time or just before or afterwards the connector needle 6 will also be forced through a septum 8b protecting the access to the cannula 9 thereby forming a fluid connection between the not shown reservoir and the cannula 9. By choosing convenient materials for the spring 15, the septum 8a and other materials being in contact with the connector 2, it should be assured that there exists a flexible connection between the connector 2 and the delivery part 3, 4. Preferably the connector 2 is fastened to the spring 15 while the movement from one position to another is guided by the walls of the central extension of the delivery part 3, 4, and the septum 8a is made of a material which is adequately soft to assure that the connector 2 is flexibly connected to the delivery part 3, 4 when the device is in a connected state. In this embodiment the connector 2 does not have to be fastened to neither the delivery part 3, 4 nor the injector part 1, the connector 2 can be a separate unit which functions as an independent interface or it can be integrated with either the delivery part 3, 4 or the injection part 1.

In fig. 12 the embodiment of fig. 11 is shown in a state where the injection part 1 is separated from the delivery part 3, 4 which leaves the spring 15 in a relaxed and extended state. In this state the through-going connector needle 6 has neither penetrated the septum 8a of the delivery part 3, 4 or the septum 8b of the injection part 1.

Fig. 13 shows the embodiment of fig. 11 and 12 in a three dimensional form. The delivery part 3, 4 and the injection part 1 joined to the base part 10 are shown from the sides where the two parts correspond to each other when joined.

The embodiment shown in fig. 11-13 can be inserted with an inserter of the type known from PCT application DK02/00640 filed on September 27, 2002. After insertion of the injection part 1, the user fastened the base part 10 to the skin. With the injection part 1 in position the user can then fastened the delivery part comprising at least one reservoir and transferring means preferably in the form of a pump to the injection part 1. If the connector 2 has the form of a separate interface the connector should be placed before the delivery part 3, 4 is fastened to the injection part and the connector will then provide for a proper fitting between the chosen injection part 1 and the chosen delivery part 3, 4.

When introducing the flexible areas as described in fig. 1-13 and as claimed it will be possible to move the releasable delivery part 3, 4 in all dimensions within certain boundaries defined by the size of the used parts as it will be possible to pull, push, lift and move the delivery part 3, 4 side wards without influencing the cannula 9 and disturbing the insertion site which would normally result in discomfort to the patient.

All the embodiments containing need to be fastened to the patients skin and this is preferably done by applying a mounting pad adhered to the proximal side of the base part 10 or to the proximal side of the infusion part 1 if the embodiment is not provided with a base part 10. The adhering of the mounting pad to the base part 10 or infusion part 1 can include glue, Velcro, moulding etc.

Fig. 14 shows an embodiment according to which it is possible to assure a fluid tight transferral of fluid from the reservoir in the delivery part 3, 4 to the cannula 9 of the injection part 1 and thereby to the patient.

In fig. 14 "A" shows the device comprising both the delivery part 3, 4 and the injection part 1 seen from the side in a three dimensional form, "B" shows the delivery part 3, 4 from below in a three dimensional form and "C" shows the injection part 1 seen from above in a three dimensional form.

Fig. 15 shows the same embodiment as in fig. 14 and is a side view of the cut illustrated by the line V-V. In fig. 15 the delivery part 3, 4 and the injection part are separated and the connector needle 6 is protected by a downward septum 8b preventing bacteria to enter the reservoir from this end. The septum 8a protecting the entrance of the reservoir is penetrated by the other end of the connector needle 6. In fig. 15 is the reservoir 4 shown positioned above the connector needle 6 and above the reservoir 4 is a reservoir lid 4ashown. The reservoir lid 4a can be removed when e.g. an ampoule constituting the reservoir 4 has to be changed. In this embodiment the reservoir 4 has flexible walls and is surrounded by a ring 16 with which it is possible to reduce the volume of the reservoir and thereby pump fluid from the reservoir 4 to the patient. In this embodiment the injection part 1 is also provided with objects 11 for fastening of the delivery part 3, 4 to the injection part formed as a circular profile standing upright from the base part 10 and being integrated with the outer surface of the housing of the injection part 1. The outward projection of the objects 11 fit with corresponding projections 13 on the delivery part 3, 4. When the delivery part 3, 4 is to be fastened to the injection part 1 the two handle portions 14 are pushed together forcing the corresponding projections 13 outwards and allowing the injection part 1 to enter the central opening in the delivery part 3, 4. When the user let go of the handle portions 14 the corresponding parts 13 return to the more central position and locks the injection part 1 to the central opening of the delivery part 3, 4.

Fig. 16 shows the same embodiment as in fig. 14 and 15 but in fig. 16 the delivery part 3, 4 and the injection part 1 are joined together as they would be during use. In this position the connector needle 6 has penetrated all three septums 8a, 8b and 8c and has created a fluid connection between the reservoir 4 and the injection part 1.

Fig. 17 shows an exploded view of an embodiment of a device according to the invention comprising a second fluid tight connection between the

reservoir of the delivery part 3, 4 and the injection part 1. This embodiment comprises a delivery part comprising a pump 3 and a reservoir, a first spring 15, an upper packing 17, a lower packing 18, a second spring 19, an injection part 1, a cannula 9, an insertion needle 20 and a mounting pad 21. Further the outward surface of the delivery part 3, 4 is provided with grooves 24 and the outward surface of the injection part 1 is provided with corresponding tongues 25.

In fig. 18 it is shown how the individual parts of the embodiment in fig. 17 works together. In this figure the inside of the injection part and the delivery part 3, 4 is illustrated. In the delivery part 3, 4 is shown a possible placement of the reservoir 4 and an outlet pipe 22 from the reservoir 4. At the outlet end, in fig. 18 the lowest end, the outlet pipe 22 is provided with a sideway directed opening and a packing which packing assures fluid tight contact between the wall of the central part of the injection part 1 and the outlet of the outlet pipe 22. The inside of the injection part 1 comprises a through-going fluid path 23 with an inlet opening sideways through the upright wall of the central part of the injection part 1.

In a first position the delivery part comprising the reservoir 4 and the pump 3 is retracted from the injection part 1, the first spring 15 is extended and the outlet from the outlet pipe 22 is blocked by the wall of the central part of the injection part 1. The lower packing 18 is in a high position where it blocks the inlet of the fluid path 23 and the second spring 19 is extended.

In a second position the delivery part 3, 4 is pushed towards the injection part 1 and both the first spring 15 and the second spring 19 are compressed. The lower packing 18, which in the first position functions as a barrier for bacteria, is pushed down by the lower edge of the delivery part 3, 4 and thereby opens the inlet of the fluid path 23. When the tongues 25 of the injection part 1 touch the upper side of the grooves 24 of the delivery part 3, 4 the downward movement of the delivery part stop and in this position the opening of the outlet pipe 22 corresponds to the inlet of the fluid path 23.

Fig. 19 shows another embodiment of a device according to the invention assuring a fluid tight connection between the reservoir and the injection part 1. This device comprises a delivery part 3, 4 e.g. as shown in fig. 1-10 but only the reservoir 4' is shown in fig.19. The device is constructed of a reservoir where the outlet is covered by a bubble shaped deformable membrane 26; this membrane prevents that micro organisms access the reservoir when the delivery part is not joined to the injection part 1. That the membrane is bubble shaped means that the membrane not has flat inner and outer surfaces but has convex inner and outer surfaces, and that the membrane does not only cover the tip of the connector needle 6 but covers a larger part of the connector needle 6. The inlet of the injection part 1 is also covered by a deformable bubble shaped membrane 27. In this embodiment the connector needle 6 is fastened to the injection part 1 but the connector needle 6 could also be fastened to the delivery part 3, 4, if the connector needle 6 is fastened to the delivery part it is necessary to provide the combined device with two needles: a connector needle 6 and a cannula 9. If the device is provided with a connector needle 6 separate from the cannula 9 it is possible to use a soft cannula.

Fig. 19A shows a three dimensional view of the device in a state where the delivery part 3, 4 and the injection part 1 are separated and fluid can not flow between the two parts. Fig. 19B shows the same state as fig. 19A but seen from a vertical cut through the device. In fig. 19C the delivery part 3, 4 and the injection part 1 has been pushed together and the fluid of the reservoir 4 can now flow through the injection part 1 and the cannula 9 to the patient. When the two membranes are pushed together membranes are deformed and the pointy connector needle 6 penetrates both membranes and forms a fluid connection, it is possible to form each of the bubble shaped membranes 26 and 27 with a varying hardness in order to control where it is desirable to penetrate the membranes by using the varying hardness to shape a base for the least deformable membrane when it is pushed against the most deformable membrane.

The membranes 26 and 27 can be made of silicone or polyurethane (PUR) or other soft polymers which can be penetrated by a needle but not by micro organisms.

The connector needle 6 is made of a relatively hard material such as metal or a hard polymer, "a relatively hard material" means that the material should at least have the strength, i.e. be hard enough, to penetrate the membranes 26 and 27.

In the embodiment of fig. 19A, B and C the connector needle 6 is one end of a single needle which at the other end functions as the cannula 9. When the connector needle 6 and the cannula is formed as one needle it will normally be made of metal or hard polymer but it can also be made of e.g. a polymer which is hardened in the connector end and unhardened and soft in the cannula end. Also the single needle can be composed of two different materials, a hard material for the connector end and a relatively soft material for the cannula end.

It is also possible to separate the connector needle 6 and the cannula 9 and produce the device according to the invention with two needles. The injector part 1 can then be provided with a commonly known soft cannula which cannula can be inserted by the help of an insertion needle attached to a separate inserter, and the connector needle 6 is made of a hard material and fastened to either the injector part 1 or the delivery part 3, 4.

In this embodiment the single needle is bend, i.e. the connector needle 6 points in a direction parallel to the patients skin while the cannula 9 points in a direction perpendicular to the patients skin. According to the present invention the connector needle 6 can point in any direction parallel or away from the patient and the cannula 9 can point in any direction according to which the cannula can be inserted into the patient's skin.

The device according to the invention can be used in connection with all kinds of medicaments and all kind of conditions where patients can benefit from a continuous intake of a drug product; preferably it is the intention to provide patients suffering from diabetes with a secure and easy-to-handle device which can provide the patient with continuously regulated doses of insulin.

In a preferred embodiment the reservoir is divided into several separate chambers where each chamber can be provided with different drug products or e.g. an active drug substance in one chamber and a solvent in another chamber, the different chambers can contain drugs of different concentrations or drugs with different active substances.

Fig. 20 - 25 show an embodiment of the invention where the connector 2 has been placed in a central position of the base plate 10 and the injection part is fastened to a peripheral part of the base plate 10. The peripheral placement of the injection part makes it possible for the user to observe the injection site. Further the injection part of this embodiment is arranged in such a way that the cannula is to be injected at an angle A deviating from 90° in relation to the distal surface of the base plate 10, normally the angle A will be between 110° and 170° where the distal surface of the base plate 10 form one side of the angle and the inserted cannula form the other side of the angle.

In this embodiment the flexible portion 12 is constructed from the base plate 10 and formed like four spokes in a wheel. It is possible to vary the flexibility of the flexible portions 12 by varying the width of the portions 12, the thickness of the base plate material 10 or the number of portions 12 (spokes).

The injection part is a two-part unit comprising a first part 1a which is fastened unreleasably to the base plate 10 and a second part 1b comprising

the cannula 9 which partly forms the fluid connection between the patient and the reservoir 4.

It is possible to position this embodiment on the skin of the patient applying at least two different methods. According to one method the base plate 10 comprising the first part 1a is first positioned on the skin of the patient and thereafter the cannula-holding second part 1b of the injection part 1 is injected e.g. with an especially adapted inserter, this method makes it possible for the user to exercise more care when positioning the base plate 10 which is normally equipped with an adhesive pad. According to a second method the base plate 10 comprising both the first part 1a and the cannula-holding second part 1b is injected all together with an inserter adapted to hold the entire device, this method comprises one less mounting step compared to the earlier described method.

In this embodiment the first part 1a is provided with inward projecting parts 1c and the second part 1b is provided with outward projecting, pivotably fastened hooks 1d. When the second part 1b is positioned in the first part 1a, the outward projecting hooks 1d are first pushed outward by the inward projecting parts 1c and after having passed the projecting parts 1c, the projecting hooks 1d return to their original position and locks the first part 1a inside the second part 1a.

The base plate 10 is provided with three upright positioned objects 11 for fastening of the delivery part 3, 4 to the base plate 10; the numbers of objects 11 are optional and the objects 11 can be either molded together with the base plate 10 or fastened to the base plate 10 after the base plate 10 has been formed e.g. by gluing or welding. The objects 11 are provided with sliding grooves 11a which sliding grooves 11a define the direction in which to move the delivery part 3, 4 when securing the delivery part 3, 4 to the base plate 10. The sliding grooves 11a correspond to protruding parts 11b on the delivery part 3, 4. In this embodiment the sliding grooves 11a are not parallel with the surface of the base plate 10 but differs in an angle B: $0° < B < 45°$

where one side of the angle B is the distal surface of the base plate 10 and the other side of the angle B is the distal edge of the sliding grooves 11a. The angle B – together with the round shape of the delivery part 3, 4 and the central position of the connector 2 - makes it possible to screw the delivery part 3, 4 on to the base plate 10.

The connector 2 is constructed of a molded body fastened unreleasably to the base plate 10 and provided with an interior compartment to which access is protected by a septum 7. The septum 7 is penetrated by the connector needle 6 when the delivery part 3, 4 is fastened to the base plate 10. From the lower part of the interior compartment and opening 5a allows fluid to enter into the flexible tube 5 and pass onto the patient through the cannula 9. The flexible tube 5 is connected to the first part 1a of the injection part and when the second part 1b of the injection part is positioned in the first part 1a a fluid path is created from the flexible tube 5 to the cannula 9.

The reservoir 4 of the shown embodiment will normally hold between 0,5 – 3 ml of fluid for transferal to the patient.

Fig. 26 – 29 shows an embodiment of the invention where the connector needle 6 is inserted directly into the injection part 1 i.e. there is no separate connection part. The injection part 1 is placed in a central position of the base plate 10 and therefore it is not possible for the user to observe the injection site.

In this embodiment the flexible portion 12 is also constructed from the base plate 10 and formed like four spokes in a wheel.

The injection part 1 is one unit comprising a molded body with an interior compartment. The interior compartment can be accessed through the protective seal 7 by the connector needle 6 when the delivery part 3 including the reservoir 4 is placed in correct position. From the interior compartment fluid can be channeled out through the cannula 9.

The base plate 10 is like the embodiment of fig. 20-25 provided with three upright positioned objects 11 for fastening of the delivery part 3, 4 to the base plate 10; the numbers of objects 11 are optional.

In the embodiment of fig. 26-29 the base plate 10 is placed on the skin of the patient simultaneously with injection of the cannula 9 of the injection part 1 and the cannula 9 is inserted in a 90° angle. In order to insert the device an inserter of the type shown in EP 1 429 826 can be used.

Fig. 30 - 32 shows an embodiment of the invention which as the embodiment of fig. 26 - 29 is without a separate connector. The injection part is placed in a central position of the base plate 10 and therefore it is not possible for the user to observe the injection site.

In this embodiment the flexible portion 12 is also constructed from the base plate 10 and formed like four spokes in a wheel.

The injection part is a two-part unit comprising a first part 1a which is fastened unreleasably to the base plate 10 and a second part 1b comprising the cannula 9. According to this embodiment the base plate 10 is positioned on the skin of the patient first and then the cannula-holding part 1b of the injection part 1 is injected in the allocated position. Like the embodiment shown in fig. 20-25 the first part 1a of this embodiment is provided with inward projecting parts 1c and the second part 1b is provided with outward projecting and pivotably fastened hooks 1d which corresponding parts can lock the second part 1b in the desired position.

Fig. 33-36 shows an embodiment of the invention where the injection part 1 is fastened to a peripheral part of the base plate 10 from which position it is possible to perform an angled injection and thereby making it possible for the user to observe the injection site. In this embodiment the injection part 1 is of the two-part type comprising a first part 1a which is fastened unreleasably to

the base plate 10 and a second part 1b comprising the cannula 9. The first part 1a is provided with inward projecting parts 1c and the second part 1b is provided with outward projecting and pivotably fastened hooks 1d.

The flexible portion 12 of this embodiment is also constructed from the base plate 10 but here the flexible portion 12 is formed like a lattice. According to this embodiment it is also possible to vary the flexibility of the flexible portions 12 by varying the width of the portions 12, the thickness of the base plate material 10 or the number of portions i.e. bars 12.

The base plate 10 is provided with two upright positioned objects 11 for fastening of the delivery part 3, 4 to the base plate 10; the numbers of objects 11 are optional and the objects 11 can be either molded together with the base plate 10 or fastened to the base plate 10 after the base plate 10 has been formed e.g. by gluing or welding. The objects 11 are provided with sliding grooves 11a which sliding grooves 11a define the direction in which to move the delivery part 3, 4 when securing the delivery part 3, 4 to the base plate 10. In this embodiment each object 11 is provided with two sliding grooves 11a, and each sliding groove 11a is inclined in an angle B: $0° < B < 90°$. The sliding grooves 11a correspond to protruding parts 11b on the delivery part 3, 4. The interaction between the sliding grooves 11a of the base plate 10 and the protruding parts 11b of the delivery part 3 assures correct insertion of the connector needle 6 through the protective seal 7 of the injection part 1b as the delivery part 3 moves along a well defined path during fastening to the base plate 10.

Generally when the injection part 1 is constructed of a two-part unit 1a, 1b the method for fastening the device to the skin of the patient will comprise the following step:

- If the base plate 10 is provided with an adhesive surface e.g. unreleasably combined to an adhesive pad, the adherent side of the base plate 10 is exposed e.g. by removing a release liner,

- the base plate 10 comprising a part of the injection part 1a is positioned on the skin of the patient,
- a second part of the injection part 1b is inserted into the position defined by the first part 1a, normally by use of an insertion device which could be a multi-use insertion device or a single-use insertion device,
- the delivery part 3 is positioned on top of the base plate 10.

Claims

1. A device for delivering fluid comprising an injection part and a fluid delivery which fluid delivery part (3, 4) and injection part can be separated and rejoined part (3, 4), the fluid delivery part comprises a reservoir (4), transferal means e.g. in form of a pump and a house (3), and the injection part comprises
- a base plate (10),
- a cannula part (1, 1b) comprising a body with a through going opening provided with a cannula (9) extending past the proximal side of the base plate (10) and
- means (21) for fixation of the base plate to the skin of the user
characterized in that the delivery part (3, 4) and the injection part is assembled through a connector (2) comprising a fluid path leading fluid from the reservoir (4) to the through-going opening in the cannula part (1, 1b) which fluid path comprises means (7, 8, 8b, 8c) for blocking access to the injection part when the connector (2) is disconnected from the delivery part (3, 4) and/or the injection part.

2. A device according to claim 1, **characterized in** that it comprises means (8, 8a) for blocking the access to the delivery part when the connector (2) is separated from this.

3. A device according to claim 1 or 2, **characterized in** that the base plate (10) is provided with fastening means (11) for connecting and disconnecting of the delivery device (3, 4) extending from the distal side of the base plate (10).

4. A device according to claim 1-3, **characterized in** that the fluid path is blocked with a membrane (7, 8, 8b, 8c) which can be penetrated by a needlelike object.

5. A device according to claim 1, **characterized in** that the delivery part and the injection part have at least two positions in relation to each other, a first position and a second position, in the first position the outlet from the reservoir (4) is blocked with a first barrier (8, 8a, 26) which is not permeable for microorganisms and the inlet of the through going opening in body of the injection part (1) is blocked with a second barrier (7, 8b, 18, 27) which is not permeable for microorganisms, in the second position an open fluid connection is formed between the reservoir (4) and the through going opening in the injection part (1) by passing the first and the second barrier.

6. A device according to claim 5, **characterized in** that one or both of the barriers (8, 8a, 26, 7, 8b, 27) comprise a material which can be penetrated by a needlelike object where the opening close on retraction of the needle like object.

7. A device according to claim 6, **characterized in** that the needlelike object is blunt.

8. A device according to claim 6, **characterized in** that the needlelike object is sharp-pointed.

9. A device according to claim 5, **characterized in** that one or both of the barriers (18) comprise a hard surface which in one position forms an opening in the area positioned between the outlet of the outlet pipe (22) and the inlet of the through going fluid path (23) and in another position close the through going fluid path.

10. A device according to claim 1-9, **characterized in** that the injection part and the delivery part (3, 4) are connected to each other by one or more flexible areas (5, 12).

11. A device according to claim 1-10, **characterized in** that the connector (2) is connected to one part by one or more non-flexible areas and connected to the other part by one or more flexible areas (5).

12. A device according to claim 11, **characterized in** that the connector (2) is connected to the injection part (1) by a flexible area (5).

13. A device according to claim 10-12, **characterized in** that at least one flexible area (5, 12) is constructed of an area with reduced material dimensions.

14. A device according to claim 10-12, **characterized in** that at least one flexible area (5, 12) is constructed of an area made by a softer and more flexible material.

15. A device according to claim 10-12, **characterized in** that at least one flexible area (5, 12) is constructed of an area made of a material which by its form has ability for extension and compression such as a material being pleated or folded.

16. A device according to claim 1-10 or12-15, **characterized in** that no non-flexible areas interconnect the injection part and the delivery part (3, 4).

17. A device according to claim 1-16, where the device comprises a relatively flat base part (10) fastened to the patient's skin, the delivery part (3, 4) is fastened to a first part of the base part (10) and the injection part (1) is fastened to a second part of the base part (10), one or more flexible areas (12) are positioned between the first part and the second part of the base part (10).

18. A device according to claim 17, **characterized in** that the delivery part (3, 4) is releasably fastened to the base part (10).

19. A device according to claim 17, **characterized in** that the connector (2) is unreleasably fastened to the base part (10).

20. A device according to claim 17, **characterized in** that the connector (2) is fastened to the first part of the base part (10).

21. A device according to claim 17, **characterized in** that the connector (2) is fastened unreleasably to the first part of the base part (10) with a non-flexible connection.

22. A device according to claim 17, **characterized in** that the flexible areas (5, 12) comprise an area (12) of the base part (10) separating the first part from the second part and a fluid connection (5) connecting the connector (2) to the injection part (1).

23. A device according to claim 1-22, **characterized in** that the at least one cannula (9) has a proximal end protruding from the proximal side of the body of the injection part.

24. A device according to claim 1-22, **characterized in** that the at least one cannula (9) has a proximal end protruding from the side of the body of the injection part.

25. A device according to claim 1-24, **characterized in** that the device is fastened to the patients skin by applying a mounting pad adhered to the proximal side of the base part (10) and/or to the proximal side of the infusion part (1).

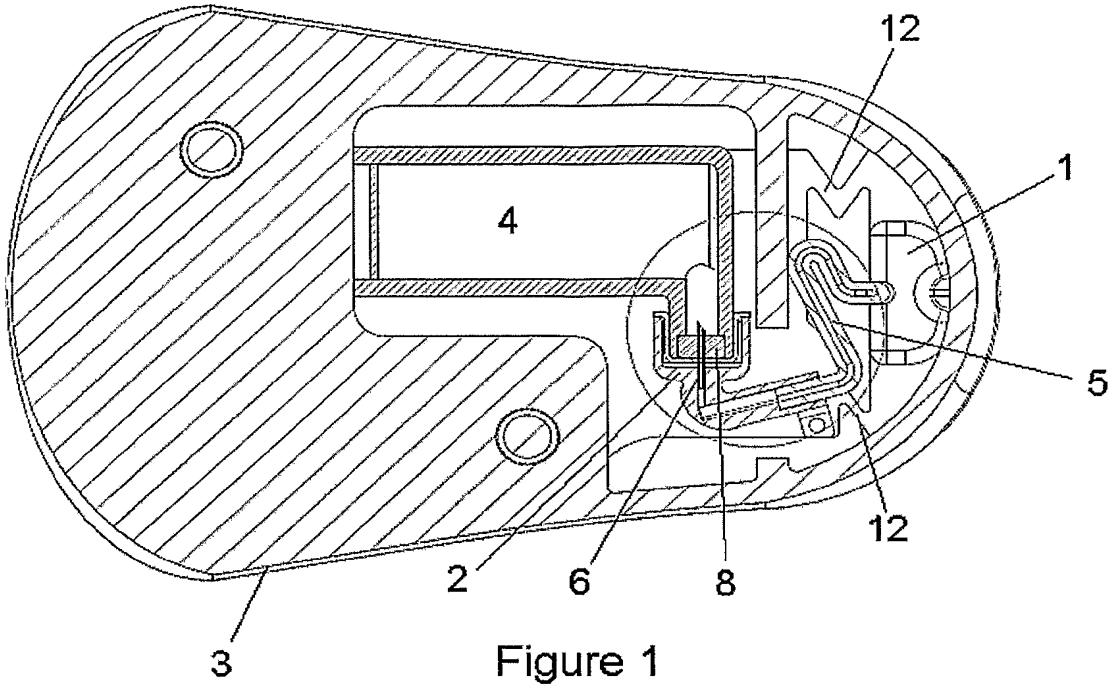
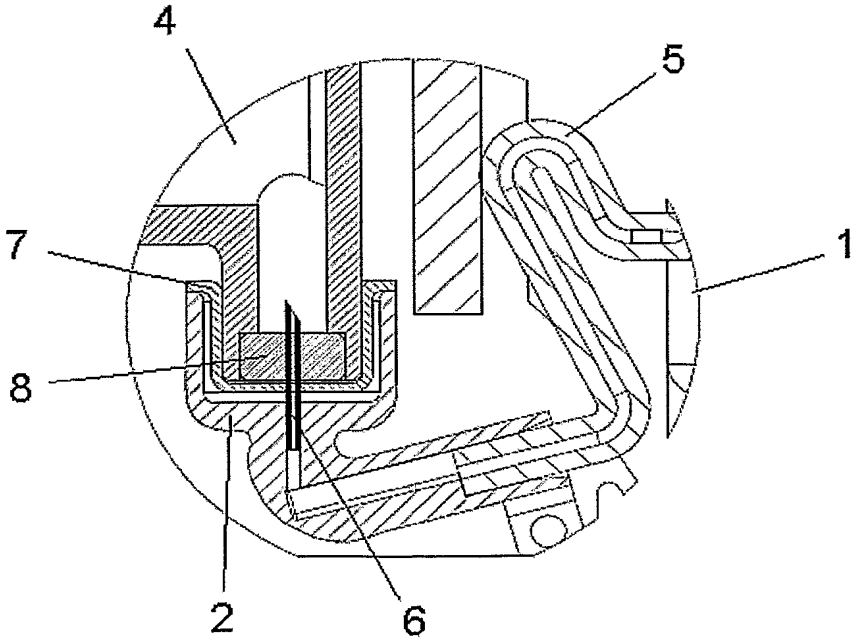


Figure 1



Figur 2

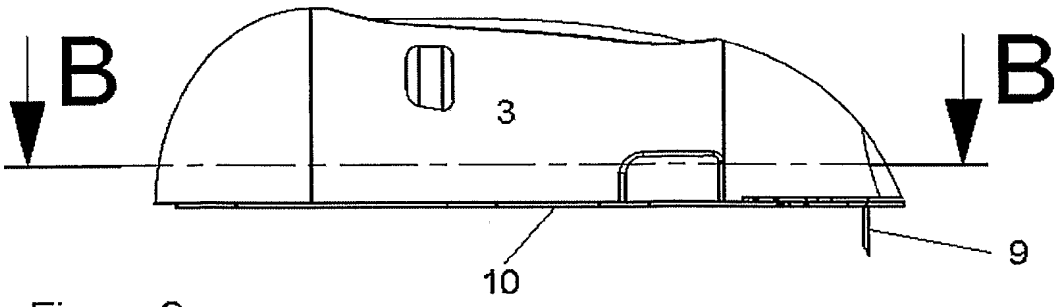


Figure 3

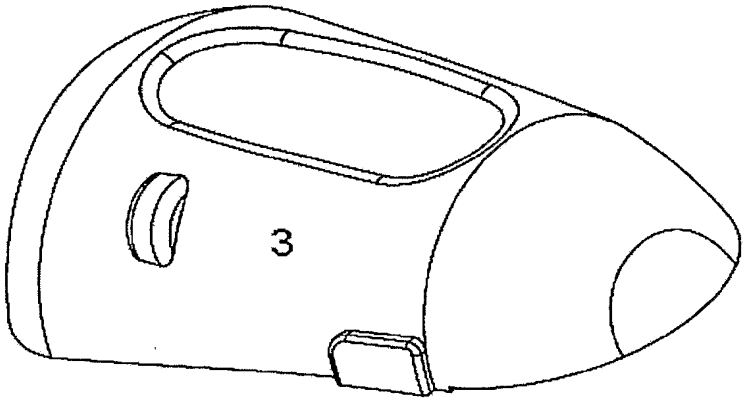
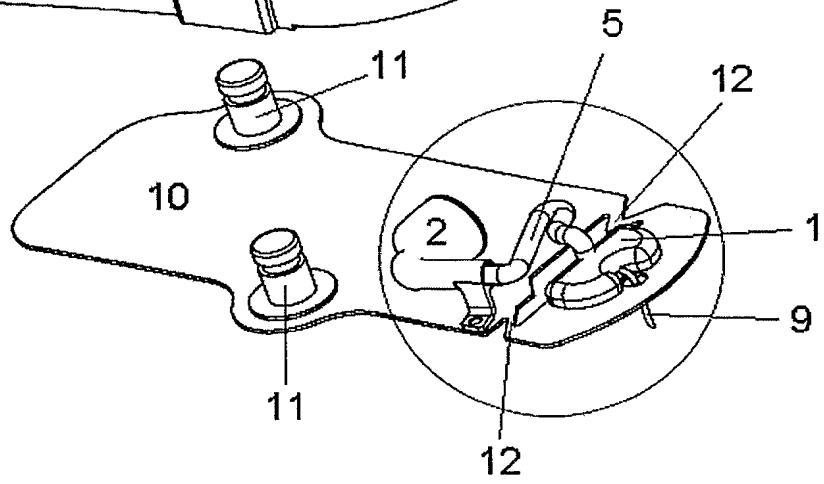


Figure 4



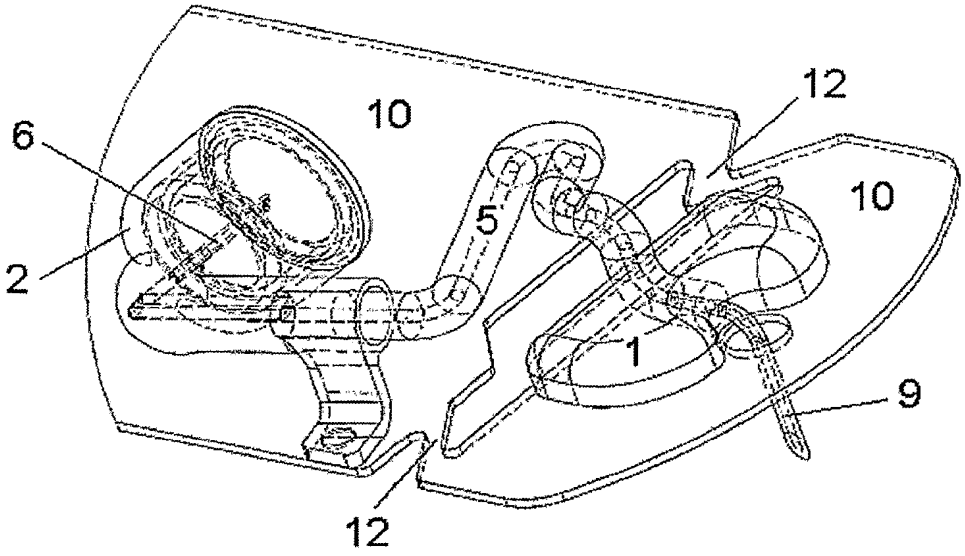


Figure 5

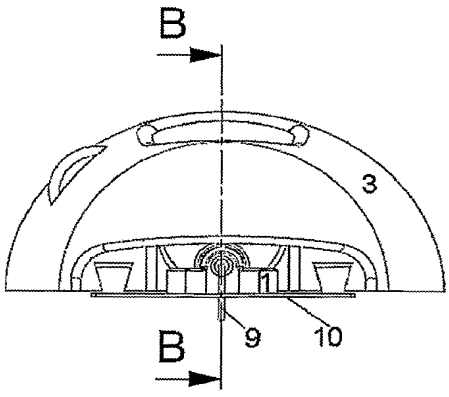


Figure 6A

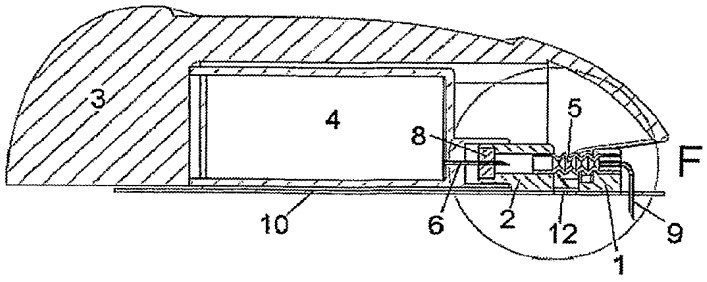


Figure 6B

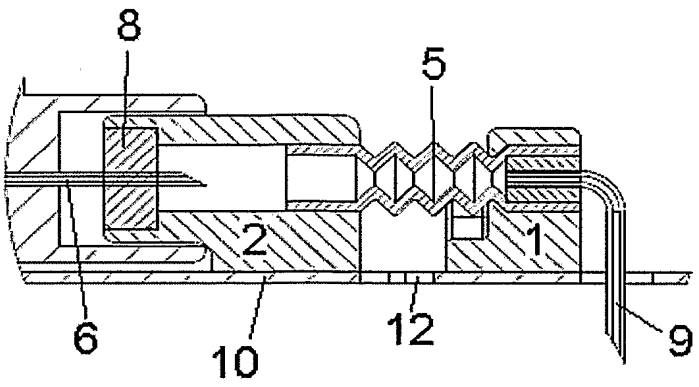


Figure 7

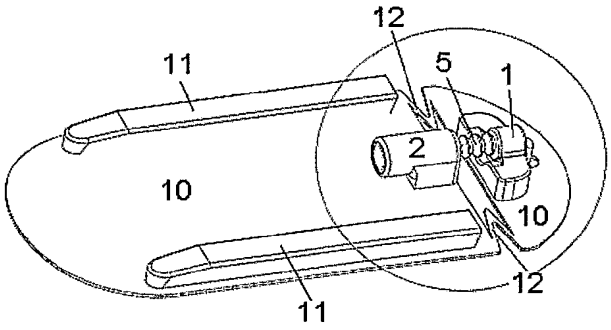


Figure 8A

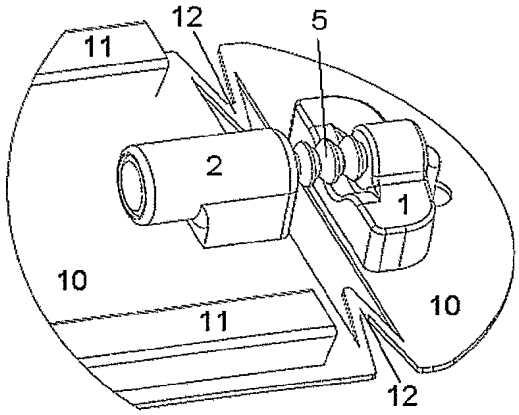
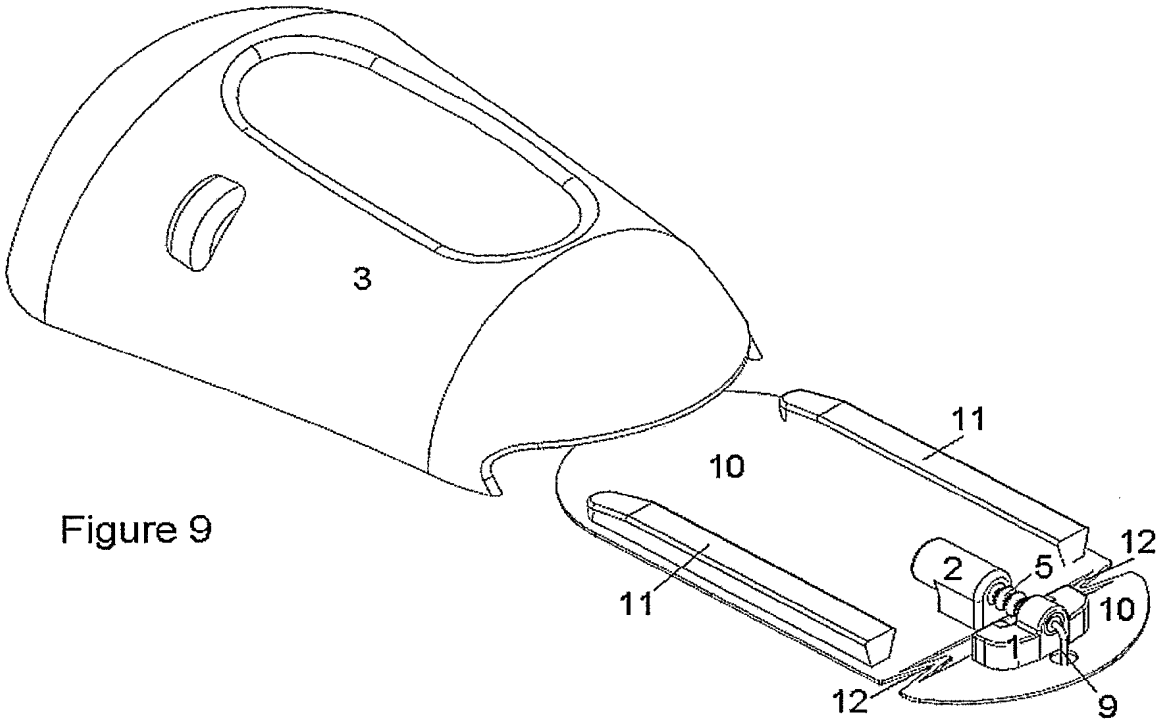


Figure 8B



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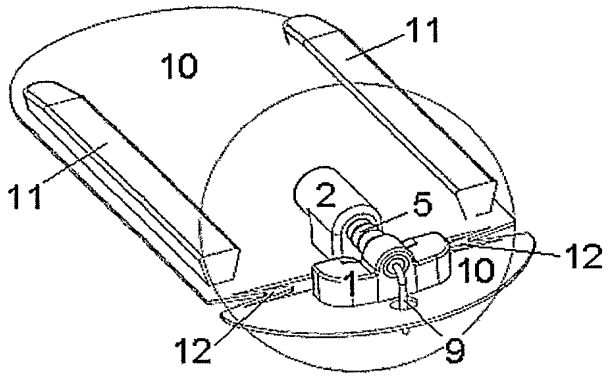

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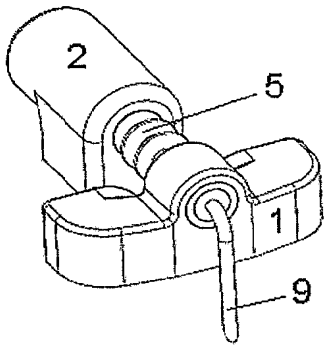
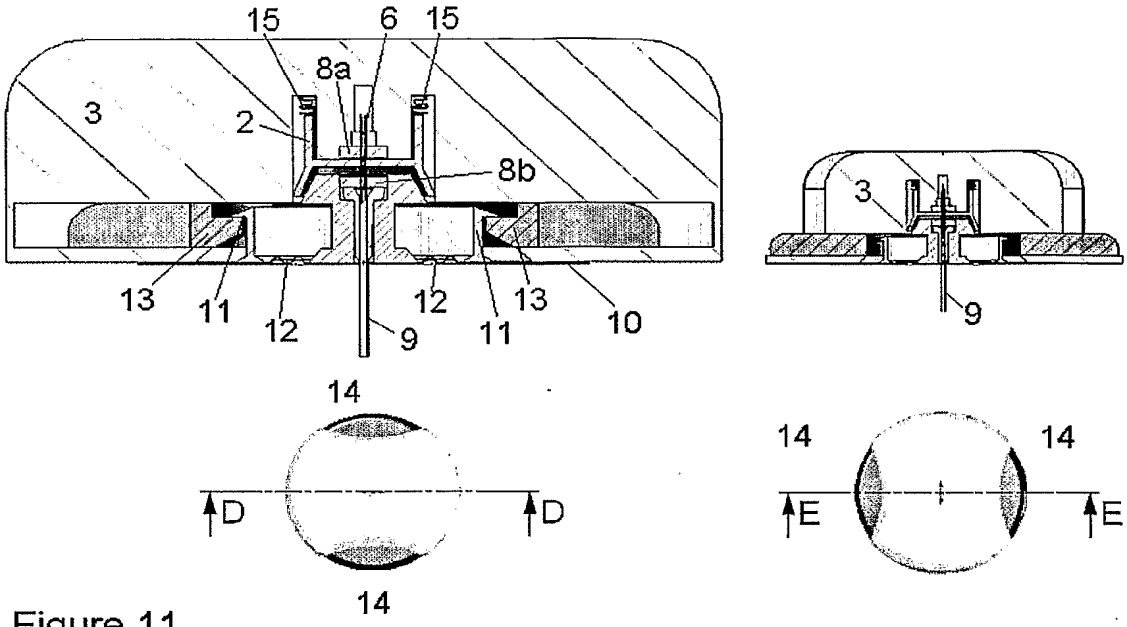


Figure 10B



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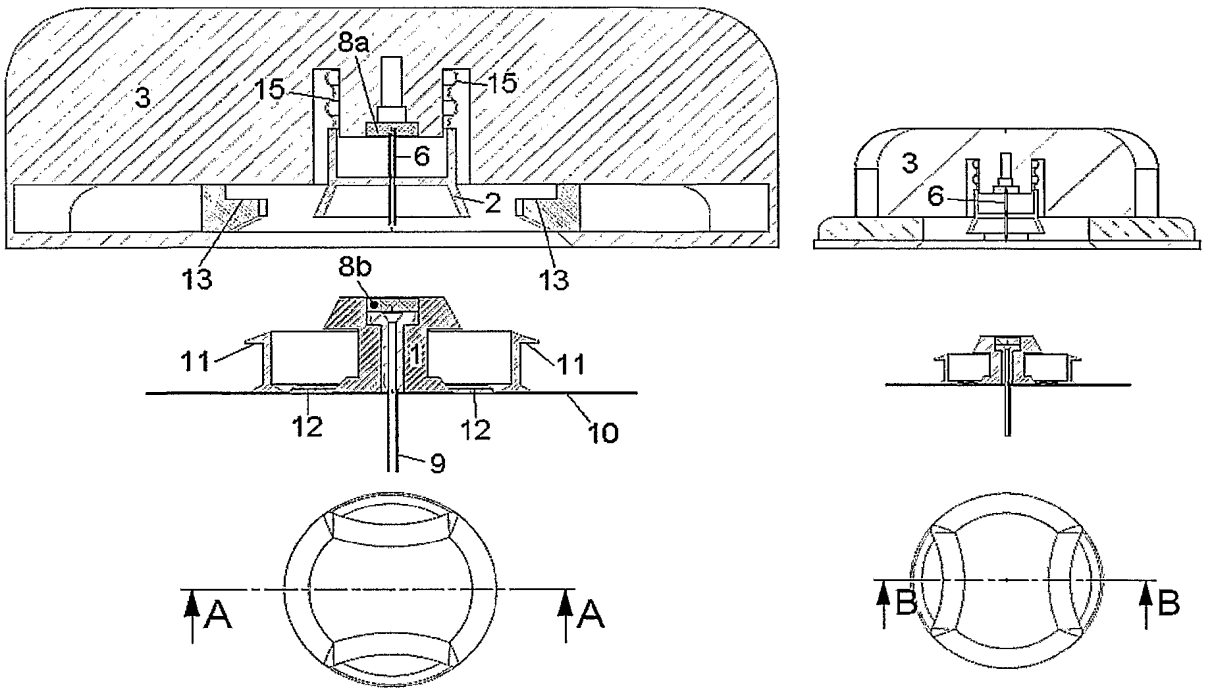


Figure 12

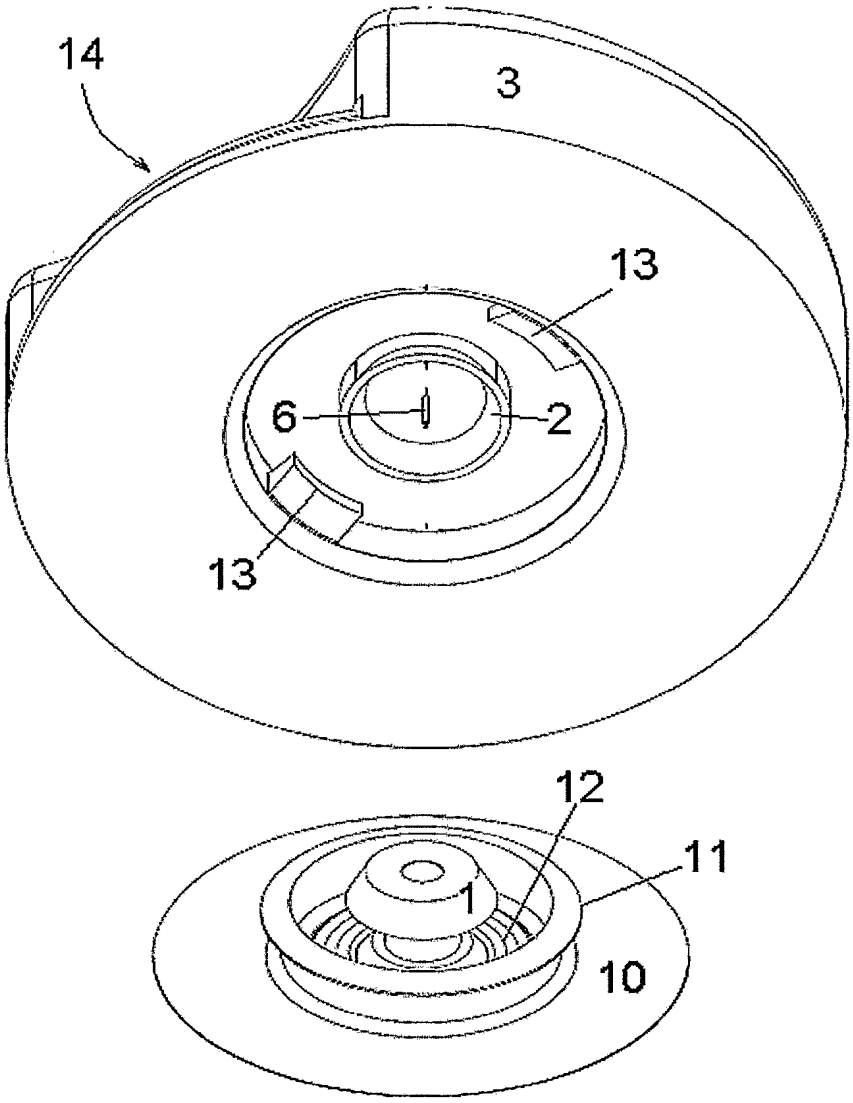
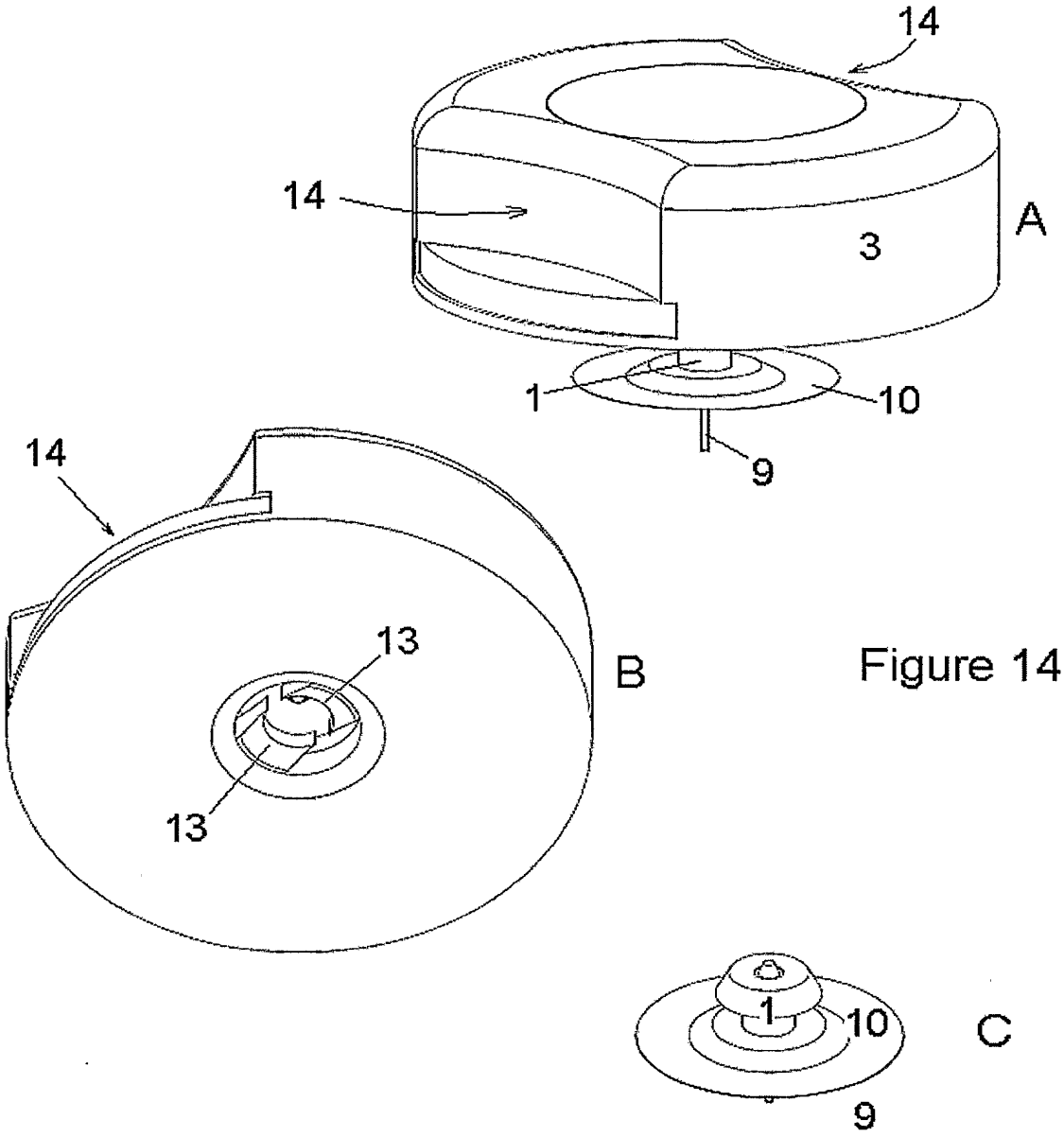


Figure 13



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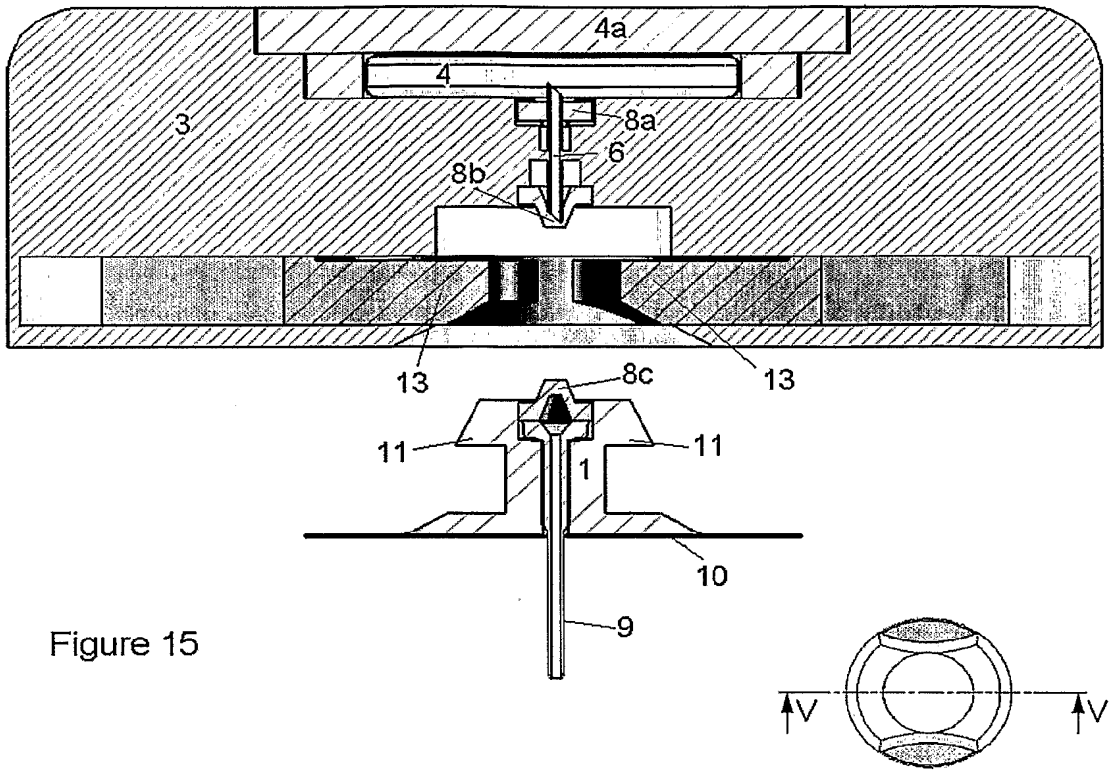
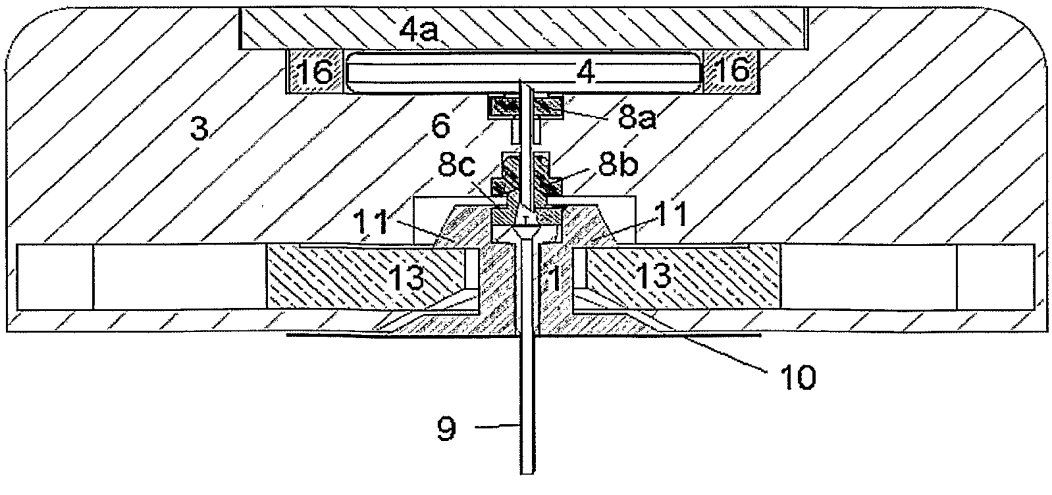


Figure 15



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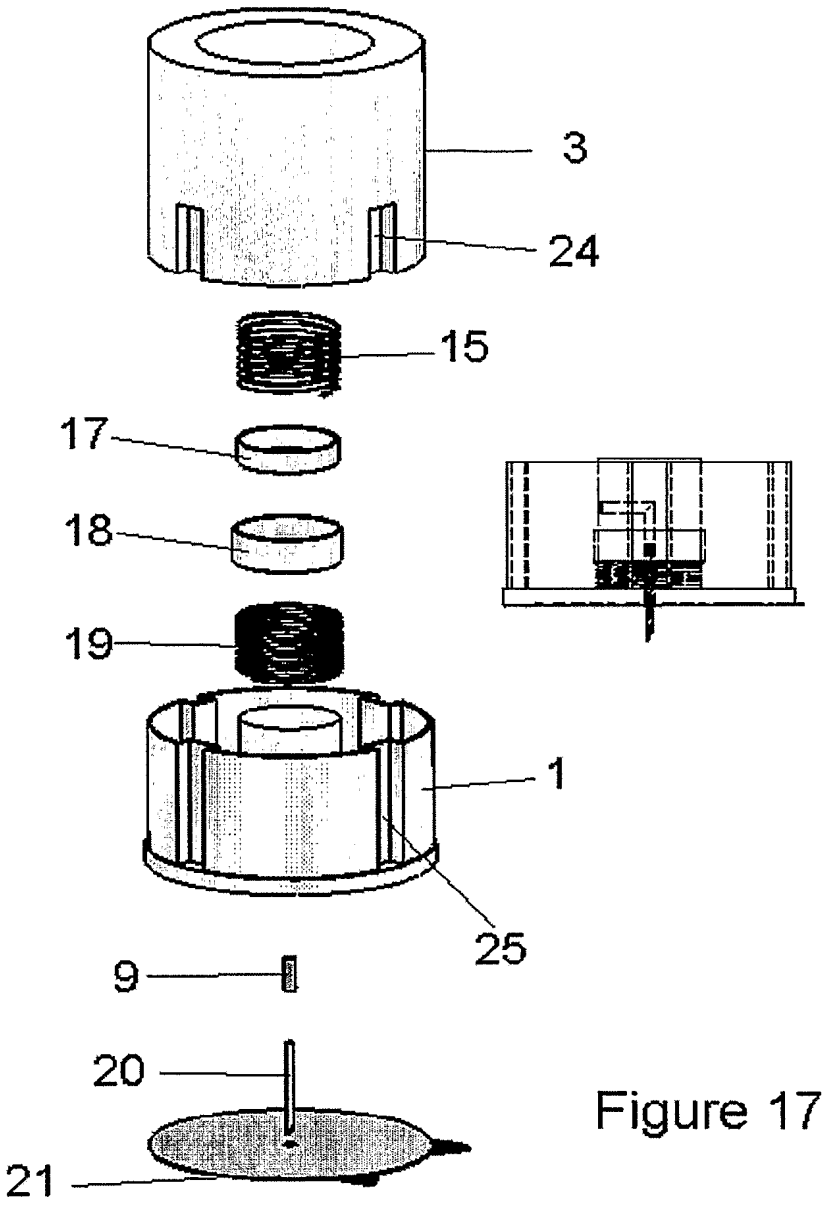

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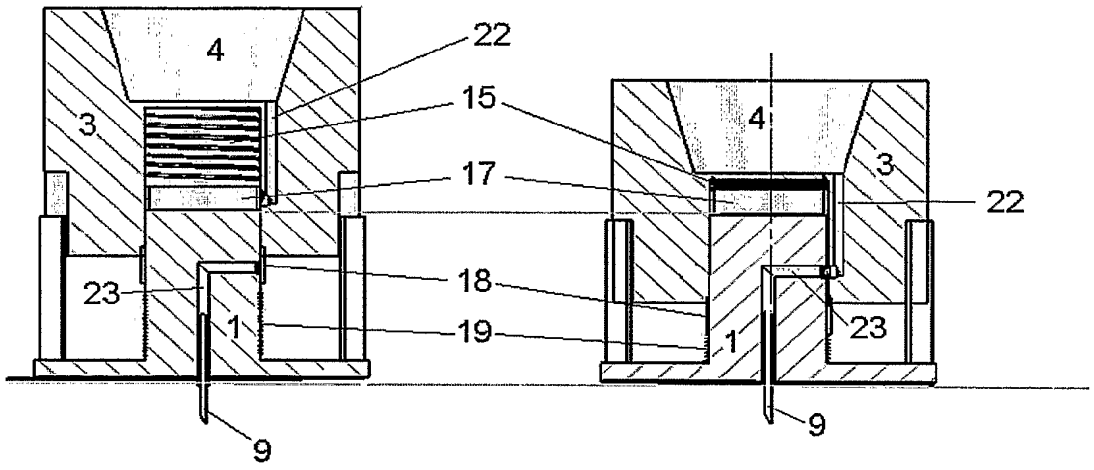
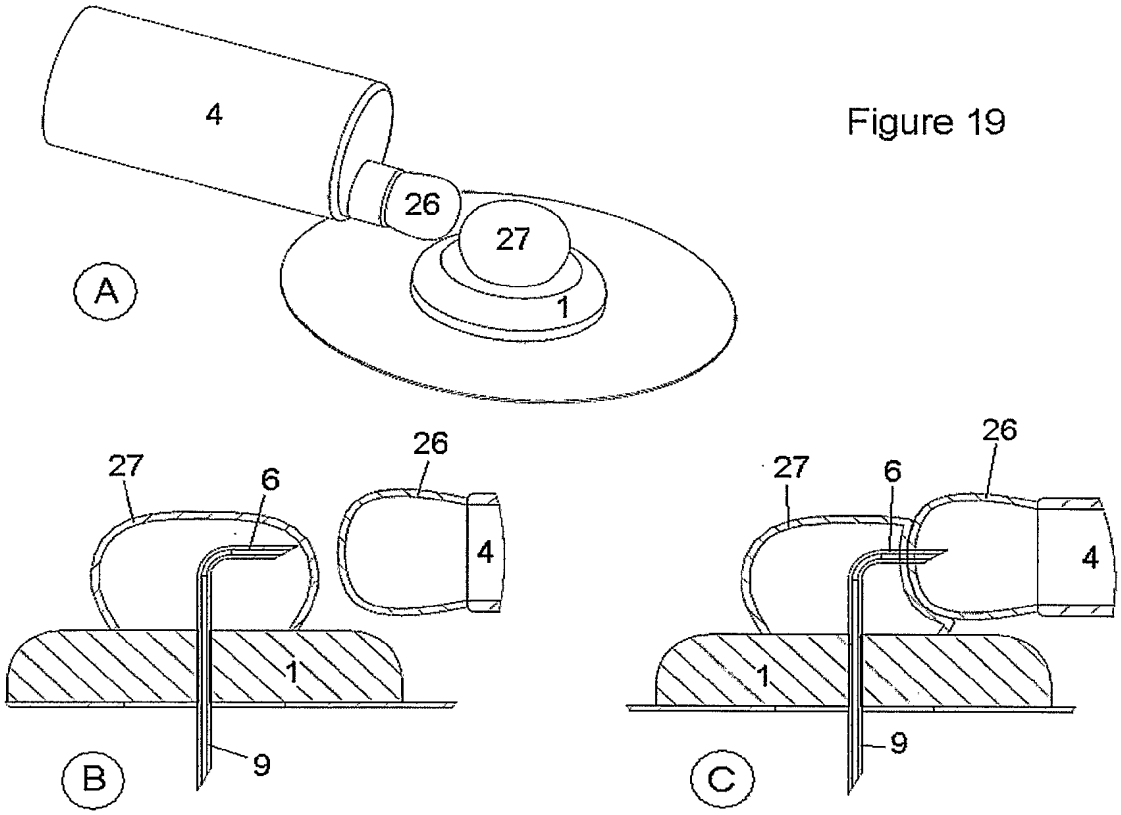


Figure 18A

Figure 18B



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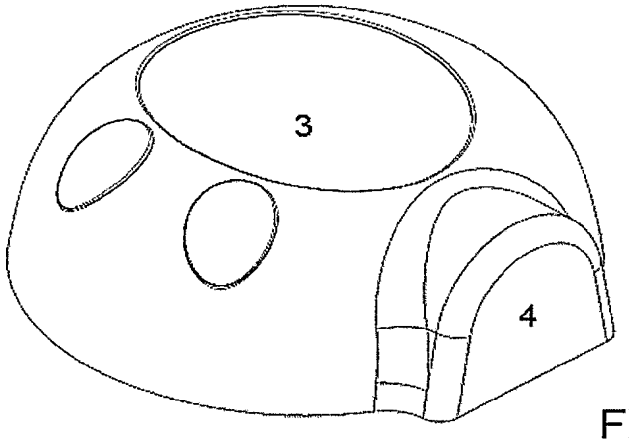
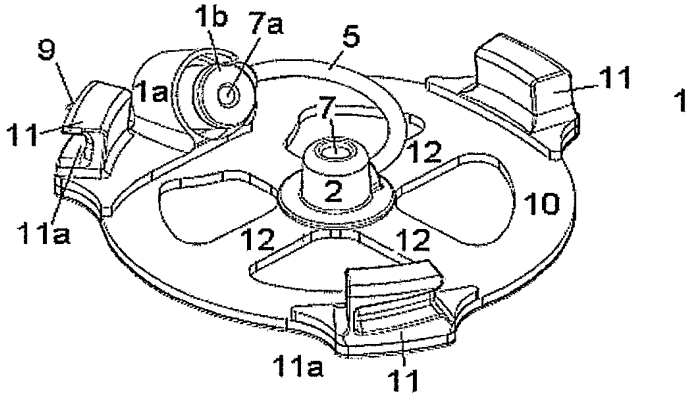
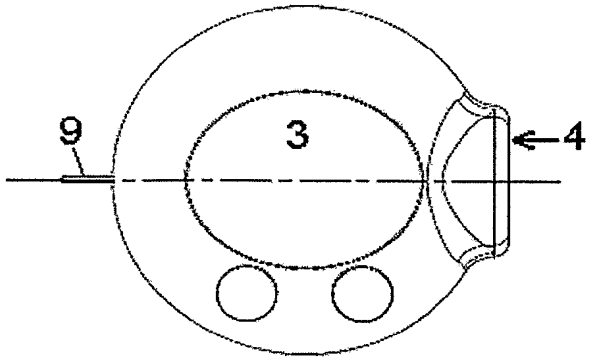


Fig. 20





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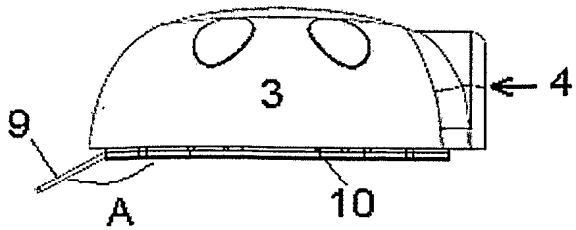

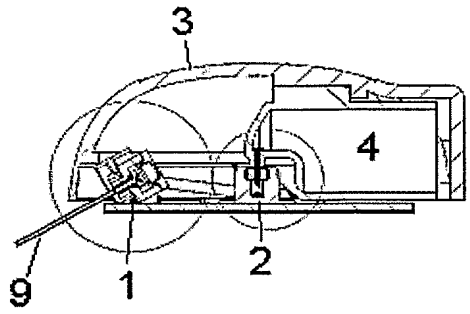

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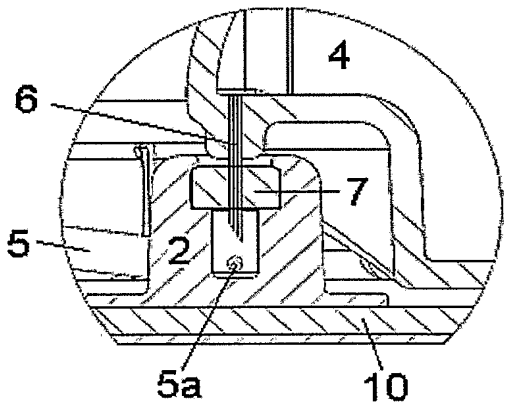

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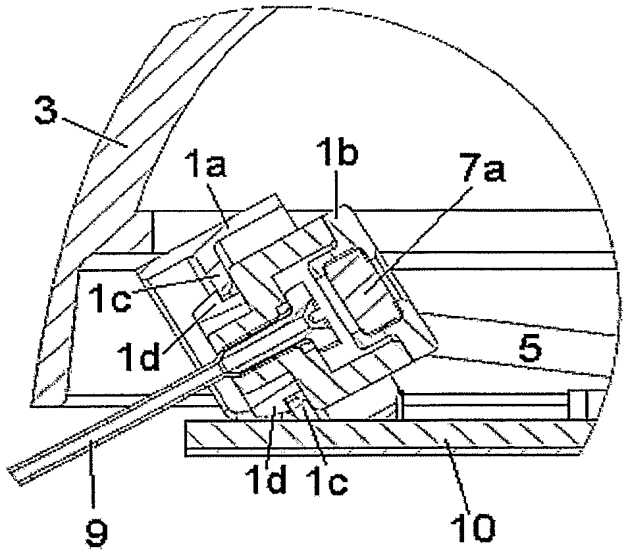

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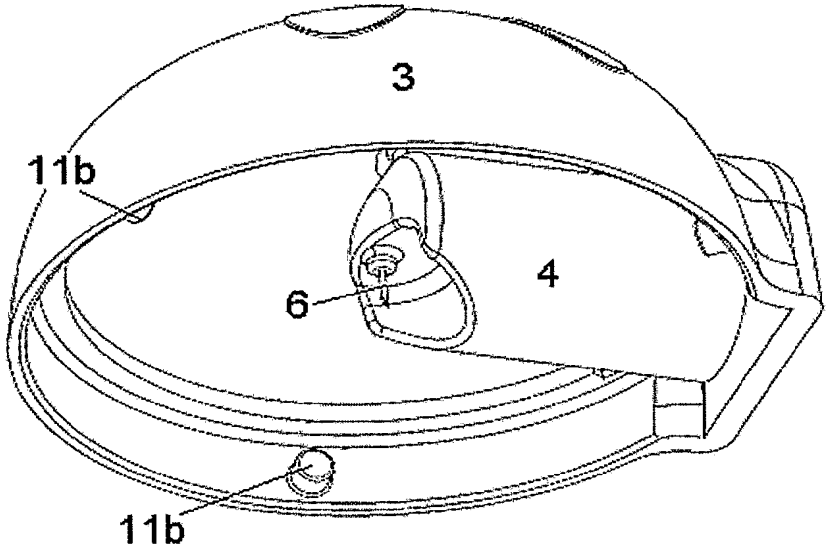

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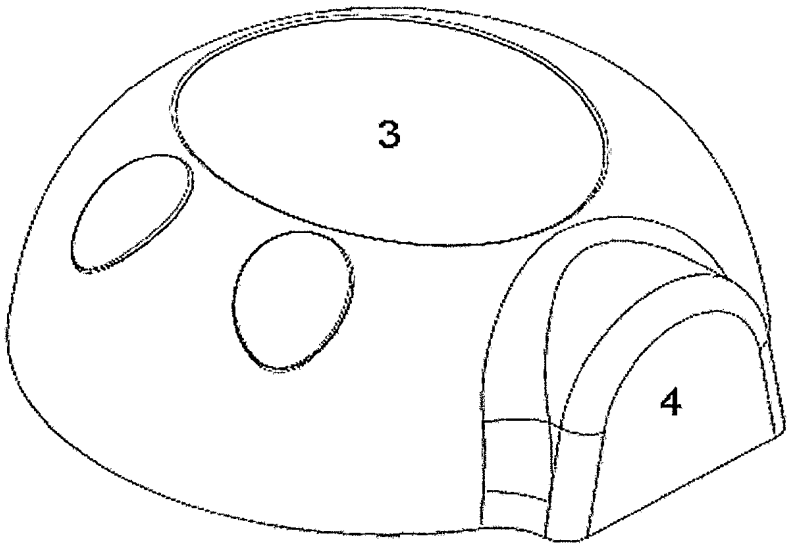

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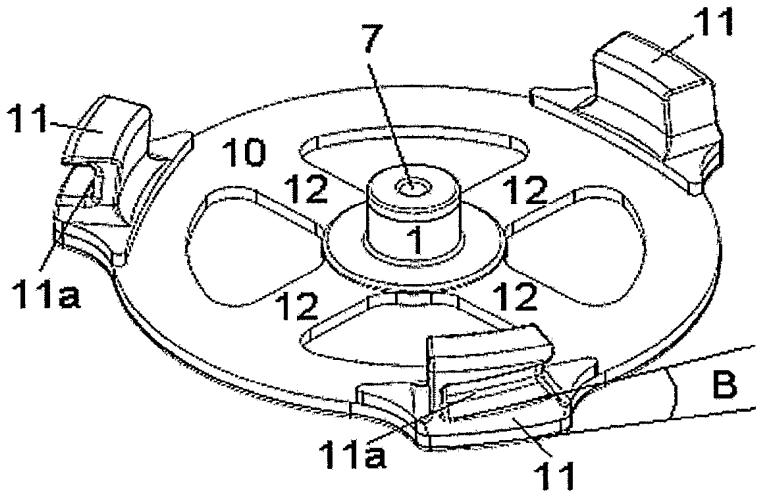

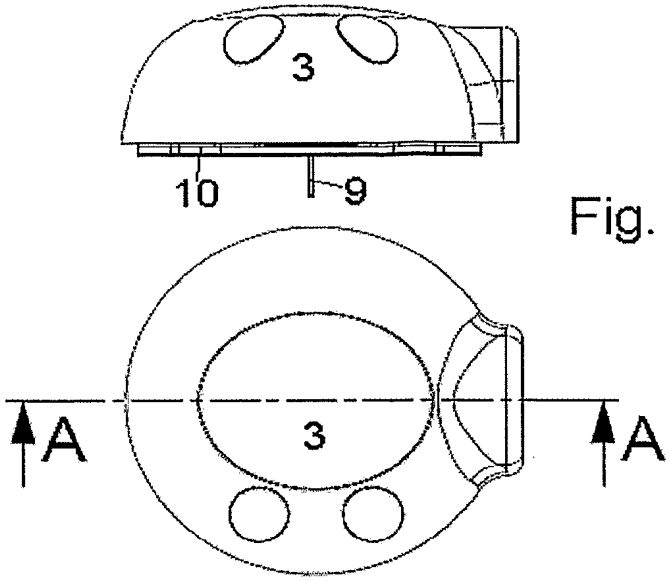

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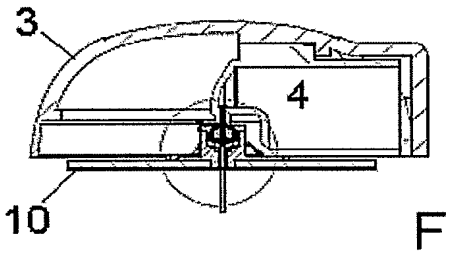

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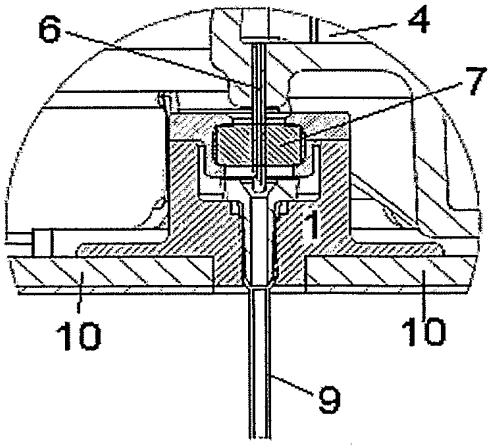

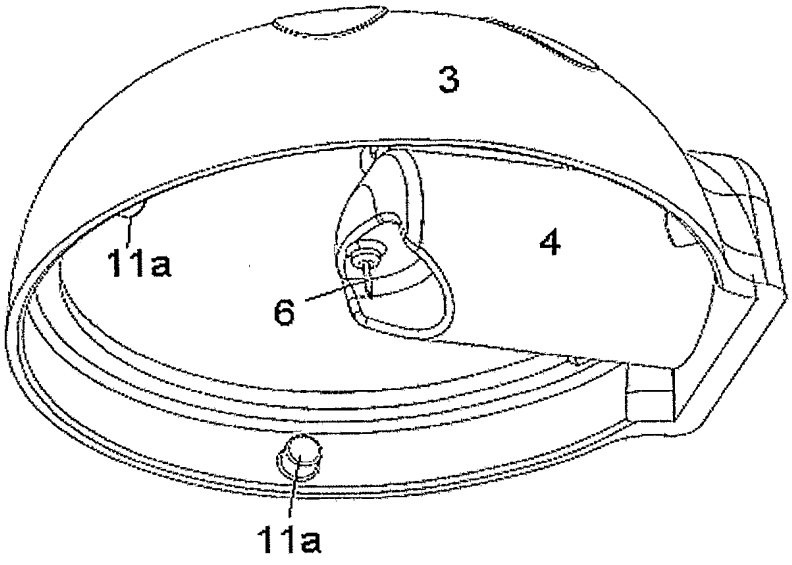

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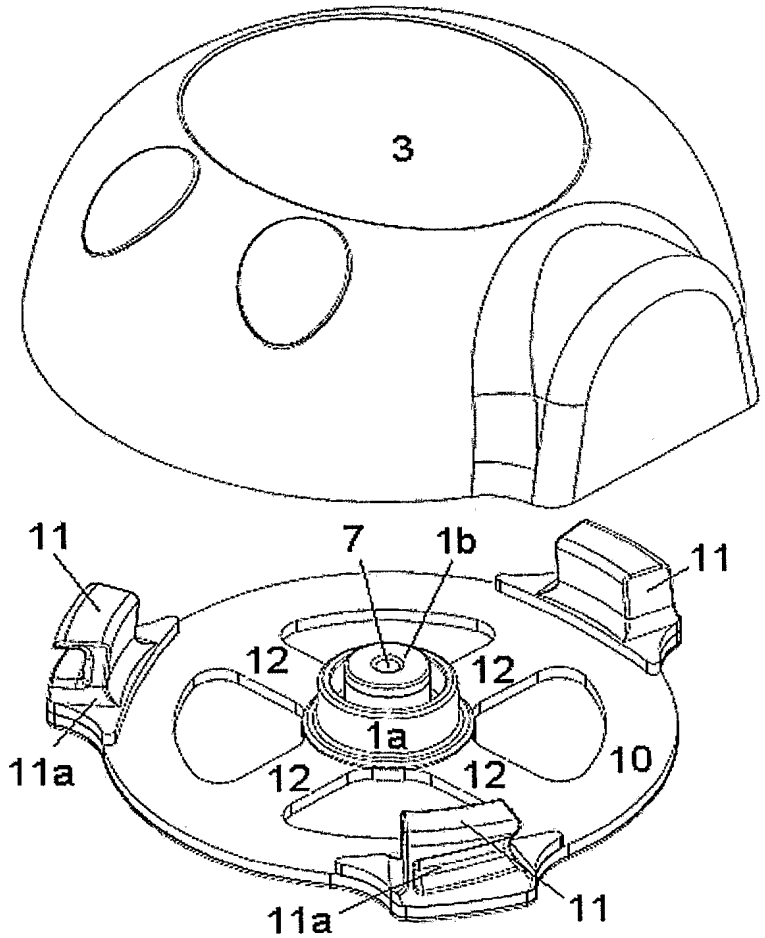

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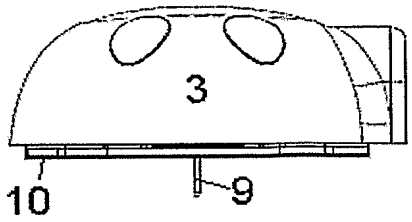

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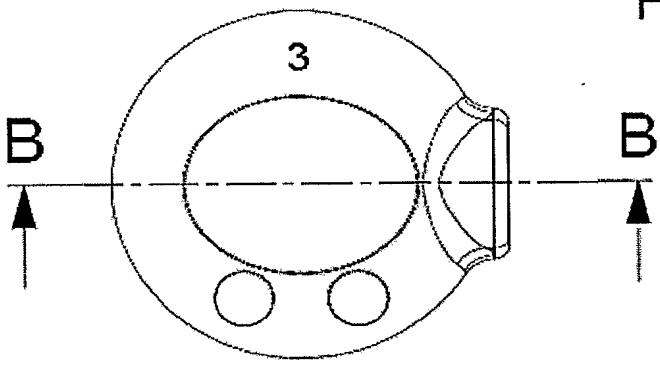

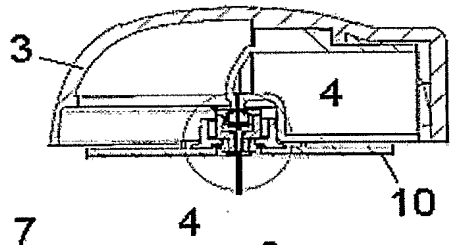

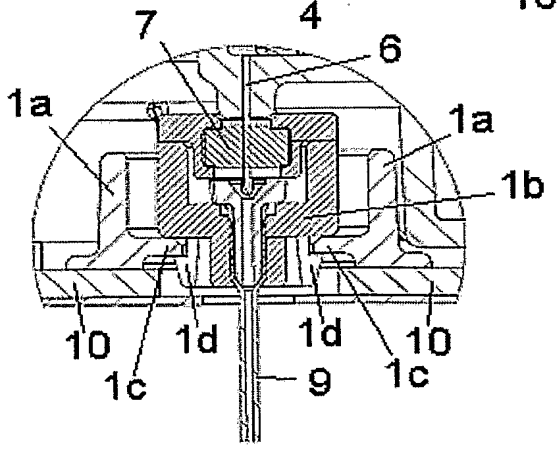

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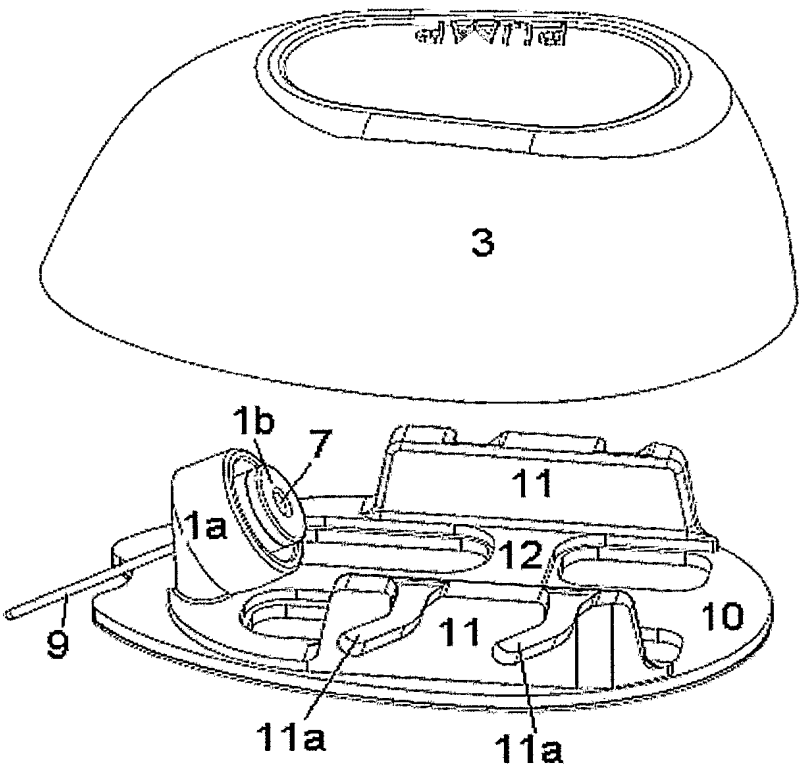

Fig. 33

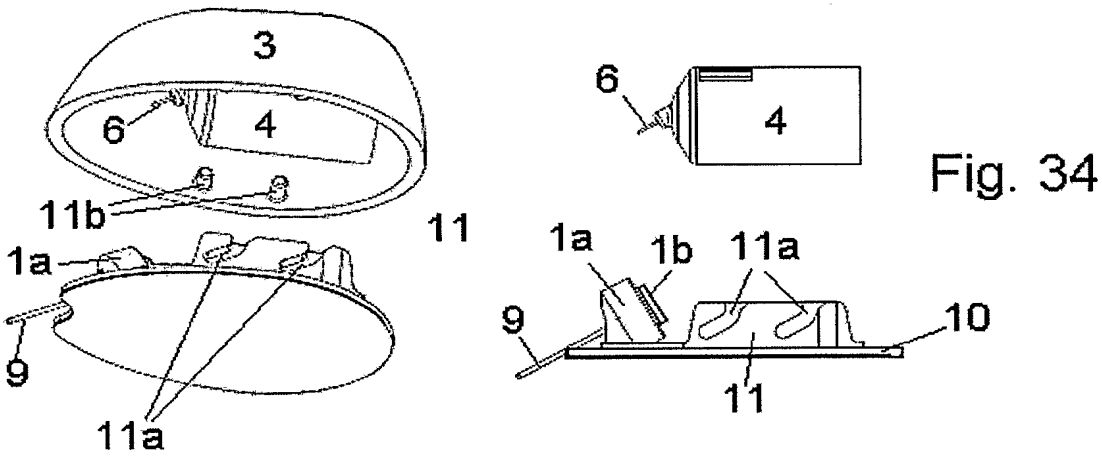

Fig. 34

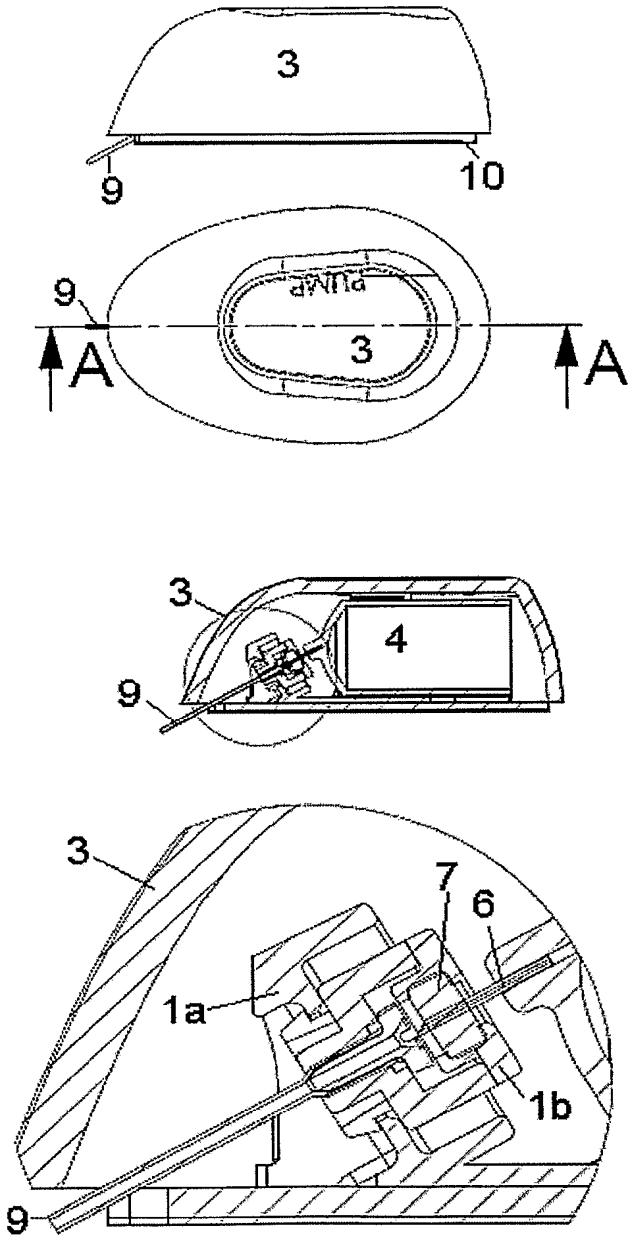

Fig. 36

INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2006/000742

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/142 A61M5/158 A61M39/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 527 792 A (NOVO NORDISK AS [DK]) 4 May 2005 (2005-05-04) cited in the application paragraphs [0049] - [0063] figures 13,14	1-16, 23-25
A	US 2004/204673 A1 (FLAHERTY J CHRISTOPHER [US]) 14 October 2004 (2004-10-14) cited in the application the whole document	1
A	WO 02/40083 A (INSULET CORPORATION) 23 May 2002 (2002-05-23) paragraphs [0066], [0071], [0072] pages 2-6,8,18	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 February 2007	01/03/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schultz, Ottmar

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INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2006/000742

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/069044 A1 (LAVI GILAD ET AL) 15 April 2004 (2004-04-15) figure 2A	1
P,X	WO 2006/032692 A (NOVO NORDISK AS [DK]; AHM THORKILD [DK]; TEISEN-SIMONY CLAUDE [DK]; RO) 30 March 2006 (2006-03-30) the whole document	1-16, 23-25

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/DK2006/000742

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1527792 A	04-05-2005	CN 1874809 A	06-12-2006
US 2004204673 A1	14-10-2004	US 2002169439 A1	14-11-2002
WO 0240083 A	23-05-2002	AT 352333 T	15-02-2007
		AU 3978102 A	27-05-2002
		CA 2427567 A1	23-05-2002
		CN 1612758 A	04-05-2005
		EP 1341569 A2	10-09-2003
		JP 2004532659 T	28-10-2004
US 2004069044 A1	15-04-2004	NONE	
WO 2006032692 A	30-03-2006	NONE	